A STUDY OF MORTALITY AMONG 6130 HOSPITALIZATIONS IN GENERAL MEDICAL WARDS IN A TERTIARY CARE HOSPITAL

A dissertation submitted in partial fulfillment of **M.D. Branch-1 (General Medicine)** examination of **The Tamilnadu Dr. M.G.R. Medical University, Chennai** to be held in **March 2007.**

CERTIFICATE

This is to certify that ***"A STUDY OF MORTALITY AMONG 6130 HOSPITALIZATIONS IN GENERAL MEDICAL WARDS IN A TERTIARY CARE HOSPITAL"*** which is submitted as thesis requirement of the MD General Medicine Branch examination of the The Tamilnadu Dr. M.G.R. Medical University is the bonafide work of the candidate:

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TABLE OF CONTENTS

INTRODUCTION

Today's health-care delivery is highly complex. Care is often delivered in a pressurized and fast-moving environment, involving a vast array of technology and several individual decisions and judgements by health-care professionals. In such circumstances things can, and do go wrong. Sometimes unintentional harm comes to a patient during a clinical procedure or as a result of a clinical decision. Errors in the process of care can result in injury. Sometimes the harm caused is serious and can even be fatal.

This problem of adverse events in health care is not new. There were studies done as early as the 1950s and 1960s on adverse events, but the subject remained largely neglected. A body of evidence started to emerge in the early 1990s with the publication of the results of the Harvard Medical Practice Study in 1991.[1,2] Subsequent research in Australia[3], the United Kingdom of Great Britain and Northern Ireland (UK)[4] and the United States of America (USA) and in particular the 1999 publication "To err is human: building a safer health system by the Institute of Medicine (IOM)"[5], provided further data and brought the subject to the top of the policy agenda and the forefront of public debate worldwide. Today more countries, including Canada, Denmark, the Netherlands, and Sweden are taking a serious look at this problem. New Zealand[6, 7] and Canada[8] have recently published research into adverse events in public Hospitals.

The Harvard study found that 4% of patients suffer some kind of harm in hospital; 70% of the adverse events result in short-lived disability, but 14% of the incidents lead to death[1, 2]. The Institute of Medicine (IOM) report estimated that "medical

errors" cause between 44 000 and 98 000 deaths annually in hospitals in the USA - more than car accidents, breast cancer or AIDS[5]. The UK Department of Health, in its 2000 report "An organisation with a Memory" estimated that adverse events occur in around 10% of hospital admissions or about 850 000 adverse events a year[13]. The Quality in Australian Health Care Study (QAHCS), released in 1995, reported an adverse-event rate of 16.6% among hospital patients[3].

The situation in developing countries and countries in economic transition merits particular attention. The poor state of infrastructure and equipment, unreliable supply and quality of drugs, shortcomings in waste management and infection control, poor performance of personnel because of low motivation or insufficient technical skills, and severe under financing of essential operating costs of health services make the probability of adverse events much higher than in industrialized nations.

Most of the current evidence on adverse events comes from hospitals, because the risks associated with hospital care are high, strategies for improvement are better documented, and the importance of patient trust is paramount. But many adverse events occur in other health-care settings, such as physicians' offices, nursing homes, pharmacies and patients' homes. Recent literature highlights concerns about outpatients as well, but there are few data on the extent of the problem outside hospitals.

Every point in the process of care giving contains a certain inherent lack of safety: side-effects of drugs or drug combinations, hazards posed by a medical device,

substandard or faulty products entering the health service, human shortcomings, or system (latent) failures. Adverse events may therefore result from problems in practice, products, procedures or systems. Adverse drug events in the Utah-Colorado Study in the USA provides a dramatic example - 75% of them being attributable to system failures.[9, 10] Similarly, most adverse events are not the result of negligence or lack of training, but rather occur because of latent causes within systems.

Despite growing interest in the safety of patients, there is still widespread lack of awareness of the problem of adverse events. Capacity for reporting, analysing and learning from experience is still seriously hampered by lack of methodological uniformity in identification and measurement, inadequate adverse event reporting schemes, undue concerns over breaches in confidentiality of data, the fear of professional liability, and weak information systems. Understanding and knowledge of the epidemiology of adverse events - frequency, causes, determinants and impact on patient outcomes, and of effective methods for preventing them are still limited. Although there are examples of successful initiatives for reducing the incidence of adverse events, none has been expanded to the level of an entire health system.

In-patient mortality[15] is probably not a good indicator of quality of care. However, it might be a starting point for clinicians to assess systematically the circumstances of death of their patients. When analysing all cases, including cases of preventable death, documenting the causes and circumstances can lead to at least two important sets of information:

i) Epidemiological data of In-hospital mortality

ii) Investigation of the circumstances of "unexpected" deaths in order to avoid them in the future.

In this respect, analysis of causes and circumstances of deaths can be a very important tool in improvement of quality of care.

Review of Literature

Evidence of Errors:

"*Mistakes are a fact of life. It's the response to the error that counts*."
—Nikki Giovanni (American poet)

Hospital mortality has been used to assess quality of care since Florence Nightingale's comparisons of hospitals in the Crimea and in London in the 19th century[17]. Wide variations in hospital mortality have been a consistent finding. Some of this variation can be explained by variables such as the case mix of patients being treated. However, much remains unexplained. Errors and other adverse events occur regularly in health care settings, but the causes, frequency, severity, preventability, and impact of these events on patient outcomes are not completely understood. A few studies have found an alarmingly high prevalence of adverse events and medical errors in some hospitals.

The Epidemiology of Medical Errors:

Studies of adverse outcomes and harm to patients have been carried out for many years. However, the absence of standardized definitions of medical error, the lack of coordination and integration of systems to report and monitor errors, and the difficulty in distinguishing preventable errors from currently unavoidable adverse events hamper our understanding of this problem. It is unlikely that we can ever know the precise frequency with which errors occur in health care settings because we must rely on people to recognize that errors were made, to distinguish them from bad outcomes of appropriate treatment, and then to report them.

As far back as 1850, Hungarian physician Ignaz Semmelweiss[18] linked transmission of infection to poor hand hygiene, but failed to persuade his colleagues to alter their behaviour. In the USA at the beginning of the 20th century, Ernest Codman, a Boston surgeon, argued for the routine assessment of outcomes. The Confidential Enquiry into Maternal Deaths in the UK dates from 1952. Many other examples could be given of isolated studies into errors and iatrogenic effects of drugs and other effects. But it was not until the 1970s that any attempt was made to provide an overview of the scale of harm and adverse outcomes. In 1977, the California medical insurance feasibility study suggested that almost 4% of patients admitted to hospital suffered some kind of adverse event.

Ivan Illich's critique Limits to medicine: medical nemesis, the expropriation of health went so far as to argue that health care was in fact a major threat to health. The rising rate of litigation in the 1970s and 1980s was another important stimulus to raising awareness of the problem of patient safety. In the USA and later elsewhere, this led to the development of risk-management programmes. Dr. Lucian L. Leape opened medicine's Pandora's Box in his 1994 JAMA paper[19], "Error in medicine". He began the paper by reminiscing about Florence Nightingale's maxim – "first do no harm." But he found evidence of the opposite happening in medicine. He found that Schimmel reported in 1964 that 20% of hospital patients suffered iatrogenic injury, with a 20% fatality rate. Steel in 1981 reported that 36% of hospitalized patients experienced iatrogenesis with a 25% fatality rate and adverse drug reactions were involved in 50% of the injuries. Bedell in 1991 reported that 64% of acute heart attacks in one hospital were preventable and were mostly due to adverse drug reactions.

Retrospective review of case records:

The most powerful evidence of harm to patients from health-care systems comes from several retrospective reviews of case records in which clinicians assessed the presence or absence of adverse events instances of harm to patients from health-care management rather than disease. The Harvard study[1, 2] found that patients were unintentionally harmed by treatment in almost 4% of hospital admissions in New York State. For 70% of these patients the resulting disability was slight or temporary, but in 7% it was permanent and 14% of these patients died, partly as a result of their treatment. Serious harm, therefore, came to about 1% of patients admitted to hospital. In the Harvard Medical Practices Study of adverse medical events (Leape, 1991), which was based on 30,195 randomly selected records from 51 hospitals in New York State, the researchers found that drug complications represented 19% of all adverse events. The researchers concluded that 58% of injuries and deaths due to drug reactions were preventable, and 27.6% of such complications were due to negligence. According to this study, antimicrobial drugs were the class of agents most commonly associated with adverse drug events. Misuse of antimicrobial drugs not only exposes individual patients to an increased risk of a poor treatment outcome, but also leads to the emergence and spread of drug-resistant microorganisms, which may place other patients and health care workers at risk of infection. The specific problem of medication errors has drawn considerable public attention, since all such errors are preventable. Medication errors - mistakes in writing prescriptions, dispensing or administering drugs - are a subset of the larger category of errors involving drugs.

In a case–control study covering a 4-year period at a single hospital, it was determined that there was an almost 2-fold increase in the risk of death attributable to such errors. In the previously cited Harvard Medical Practice Study, 19.4% of all disabling adverse events were caused by drugs, of which 45% were due to medication errors. In that study, 30% of those with drug-related injuries died. In addition to drug-related injuries and deaths that occur in hospitals, information is available indicating that preventable, drug-related injuries are also occur at a high frequency among out-patients.

Studies on side effects from drugs:

In a study of 1,000 ambulatory patients drawn from a community, office-based medical practice (Burman, 1976), the researchers noted side effects from drugs in 42 patients (4.2%), including 23 who experienced preventable side effects. Well-understood drug–drug interactions are preventable, but there is evidence that physicians do not routinely screen for them, even when a patient's medication history is readily available. In a study of 424 randomly selected visits to a hospital emergency department (Beers, 1990), 47% of visits resulted in the patient receiving a prescription for a medication. In 10% of these instances, the new medication could potentially harm the patient due to an avoidable drug-drug interaction. In all of these cases, a medication history had been recorded and available to the prescribing physicians. Thus, it can be seen that preventable and avoidable injuries due to drugs constitute a significant public health concern. The increasing use of drugs, the growing fragmentation of health care delivery, and the competing demands of an overburdened health care delivery system will, undoubtedly, accentuate these problems. The Harvard study was initially commissioned to assess the potential for no-fault compensation in New York State, but its major legacy

has been to reveal the scale of harm to patients from health care and to stimulate a number of similar studies.

Corroborating studies:

The findings of the Harvard Medical Practice Study in New York have been corroborated by a study of adverse events in Colorado and Utah[9] in USA in 1992. This study included the review of medical records pertaining to a random sample of 15,000 discharges from a representative sample of hospitals in the two states. Adverse events occurred in 2.9% of hospitalizations in each state. Over four out of five of these adverse events occurred in the hospital, the remaining occurred prior to admission in physicians' offices, patients' homes or other non-hospital settings. The proportion of adverse events due to negligence was 29.2%, and the proportion of adverse events that were preventable was 53%. As was the case in the New York study, over 50% of adverse events were minor, temporary injuries. But the study in New York found that 13.6% of adverse events led to death, as compared with 6.6% in Colorado and Utah. In New York, about one in four negligent adverse events led to death, while in Colorado and Utah, death resulted in about 1 out of every 11 negligent adverse events. Factors that might explain the differences between the two studies include: temporal changes in health care, and differences in the states' patient populations and health care systems. Both the study in New York and the study in Colorado and Utah identified a subset of preventable adverse events that also satisfied criteria applied by the legal system in determining negligence. It is important to note that although some of these cases may stem from incompetent or impaired providers, the committee believes that many could likely have been avoided had better systems of care been in place.

Studies on effects of adverse events – North American experience

Extrapolation of the results of the Colorado and Utah study[10] to the over 33.6 million admissions to hospitals in the United States in 1997 implies that at least 44,000 Americans die in hospitals each year as a result of preventable medical errors. Based on the results of the New York study, the number of deaths due to medical error may be as high as 98,000. By way of comparison, the lower estimate is greater than the number of deaths attributable to the 8th-leading cause of death.

Some maintain these extrapolations likely underestimate the occurrence of preventable adverse events because these studies: considered only those patients whose injuries resulted in a specified level of harm; imposed a high threshold to determine whether an adverse event was preventable or negligent concurrence of two reviewers); and included only errors that are documented in patient records. Two studies that relied on both medical record abstraction and other information sources, such as provider reports, have found higher rates of adverse events occurring in hospitals. In a study of 815 consecutive patients on a general medical service of a university hospital[5], it was found that 36% had an iatrogenic illness, defined as any illness that resulted from a diagnostic procedure, from any form of therapy, or from a harmful occurrence that was not a natural consequence of the patient's disease. Of the 815 patients, 9% had an iatrogenic illness that threatened life or produced considerable disability, and for another 2%, iatrogenic illness was believed to contribute to the death of the patient.

In a study of 1,047 patients admitted to two intensive care units and one surgical unit at a large teaching hospital[8], 480 (45.8 %) were identified as having had an adverse

event, where adverse event was defined as "situations in which an inappropriate decision was made when, at the time, an appropriate alternative could have been chosen." For 185 patients (17.7 %), the adverse event was serious, producing disability or death. The likelihood of experiencing an adverse event increased about 6% for each day of hospital stay[20]. In a study of 182 deaths in 12 hospitals from three conditions (cerebrovascular accident, pneumonia, or myocardial infarction), it was found that at least 14% and possibly as many as 27% of the deaths might have been prevented[21]. A 1991 analysis of 203 incidents of cardiac arrest at a teaching hospital, found that 14% followed an iatrogenic complication and that more than half of these might have been prevented. In a study of 44,603 patients who underwent surgery between 1977 and 1990 at a large medical center, 2,428 patients (5.4%) suffered complications and nearly one-half of these complications were attributable to error. Another 749 died during the same hospitalization; 7.5% of these deaths were attributed to error[5].

Studies on effects of adverse events – Australia and Europe

A parallel Australian study[3] found a 16.6% adverse events rate, where about half the cases were judged preventable, but with a similar number of serious incidents to that in the USA studies. In the UK a review of patient records indicated a 10.8% adverse events rate, again about half being preventable. Findings in Denmark, New Zealand and Canada also suggest a relatively high rate of adverse events around 10%. The financial cost of adverse events, in terms of additional treatment and extra days in hospital, is vastly greater than the costs of litigation. In the UK the cost of preventable adverse events is estimated to be £ 1000 million per annum in lost bed days alone. The wider costs of lost working time, disability benefits and the wider economic consequences are greater

still. There is also an enormous human cost. Many patients suffer increased pain, disability and psychological trauma and may experience failures in their treatment as a terrible betrayal of trust. Staff may experience shame, guilt and depression after making a mistake, with litigation and complaints imposing an additional burden. Doctors or nurses whose confidence has been impaired will work less effectively

Table1. Data on adverse events in health care from several countries

Study	**Study focus (date of admissions)**	**Number of hospital admissions**	**Number of adverse events**	**Adverse event rate (%)**
USA (New York State) (Harvard Medical Practice Study) [1, 2]	Acute care hospitals (1984)	30 195	1 133	3.8
USA (Utah-Colorado Study (UTCOS))1 [10]	Acute care hospitals (1992)	14 565	475	3.2
USA (UTCOS)[10]	Acute care hospitals (1992)	14 565	787	5.4
Australia (Quality in Australian Health Care Study (QAHCS))[3]	Acute care hospitals (1992)	14 179	2 353	16.6
Australia (QAHCS)2	Acute care hospitals (1992)	14 179	1 499	10.6
UK[4]	Acute care hospitals	1 014	119	11.7
Denmark[12]	(1999-2000)	1 097	176	9.0
New Zealand [6, 7]	Acute care hospitals (1998)	6 579	849	12.9
Canada[8]	Acute care (1998)	3 720	279	7.5

1. UTCOS revised using the same methodology as the Quality in Australia Health Care Study (harmonizing the four methodological discrepancies between the two studies).
2. QAHCS revised using the same methodology as UTCOS (harmonizing the four methodological discrepancies between the two studies).

and efficiently; at worst they may abandon medicine as a career. The consequences of adverse events in advanced health-care systems are therefore huge. In less-developed health-care systems they may be greater still in relation to the benefits derived from the system.

Attention to patient safety:

Several important new initiatives in the past five years underline the increasing attention being paid to patient safety. In the USA, organizations such as the National Patient Safety Foundation are pioneering a much more sophisticated approach to patient safety, drawing on research and practice from a number of different industries. The report of the Institute of Medicine, To err is human: Building a safer health system, which starkly sets out the scale of harm to patients and has an ambitious and radical agenda for change, attracted presidential backing in the USA. In Australia, the results of the Quality in Australian Health Care Study were initially marked by political interest, which influenced the implementation programme that was to follow. High-profile cases in several countries, such as the Bristol inquiry into paediatric cardiac surgery in the UK and the similar Winnipeg inquiry in Canada, also played a part in raising public awareness and driving policy change. In the UK, the Department of Health commissioned a major report for the National Health Service that covered similar ground to the Institute of Medicine report, which in turn has led to the creation of the National Patient Safety Agency. The British Medical Journal devoted an entire issue to the subject of medical error in a determined effort to move the subject to the mainstream of academic and clinical enquiry, and other leading journals are now running series on patient safety.

Reporting of adverse incidents – a tip of the iceberg? [5]

According to a study in two obstetrical units in the U.K., only about one quarter of the adverse incidents on the units are ever reported for reasons of protecting staff or preserving reputations, or fear of reprisals, including law suits. An analysis by Wald and Shojania found that only 1.5% of all adverse events result in an incident report, and only 6% of adverse drug events are identified properly. The authors learned that the American College of Surgeons gives a very broad guess that surgical incident reports routinely capture only 5-30% of adverse events. In one surgical study only 20% of surgical complications resulted in discussion at Morbidity and Mortality Rounds. From these studies it appears that all the statistics that are gathered may be substantially underestimating the number of adverse drug and medical therapy incidents. It also underscores the fact that our mortality statistics are actually conservative figures.

Standard medical pharmacology texts admit that relatively few doctors ever report adverse drug reactions to the FDA. The reasons range from not knowing such a reporting system exists to fear of being sued because they prescribed a drug that caused harm. However, it is this tremendously flawed system of voluntary reporting from doctors that we depend on to know whether a drug or a medical intervention is harmful. It remains that whatever figure you choose to believe about the side effects from drugs, all the experts agree that you have to multiply that by 20 to get a more accurate estimate of what is really occurring in the burgeoning “field” of iatrogenic medicine.

Further examples could be given of initiatives in Canada, in several European countries, and in Asia of an increasing interest in research on patient safety and practical approaches to the management of risk. As awareness of the international nature of the problem has grown, other countries have moved more quickly towards action. Japan's patient safety programme was triggered by a single major incident, although this was thought to be symptomatic of more widespread problems. Research has not been limited to establishing the prevalence of adverse events or medical errors within health-care systems.

Effects of health-care-associated infections:

Infection complicates the treatment and care of millions of patients worldwide every year. As a result, some patients become more seriously ill than they would have been otherwise, some have prolonged stays in hospital, some experience long-term disability and some die. Because of health-care-associated infection, as well as the human costs, health-care systems carry a massive additional financial burden. Health-care associated infection presents the main characteristics of a major patient safety problem; it affects large numbers of patients worldwide; it has multiple causes, with many factors relating to the systems and processes of care provision and others to human behaviour; it cannot be eliminated but some health-care institutions have controlled the problem and the risks to patients much better than others (there is thus a patient safety improvement gap). The rate of nosocomial infections per 1,000 patient days has increased 36% - from 7.2 in 1975 to 9.8 in 1995 [15]. Reports from more than 270 U.S. hospitals showed that the nosocomial infection rate itself had remained stable over the previous 20 years with

approximately five to six hospital-acquired infections occurring per 100 admissions, which is a rate of 5-6% However, because of progressively shorter inpatient stays and the increasing number of admissions, the actual number of infections increased. It is estimated that in 1995, nosocomial infections cost $4.5 billion and contributed to more than 88,000 deaths - one death every 6 minutes. The 2003 incidence of nosocomial mortality is quite probably higher than in 1995 because of the tremendous increase in antibiotic-resistant organisms. Morbidity and Mortality Report found that nosocomial infections cost $5 billion annually in 1999. This is a $0.5 billion increase in four years. The present cost of nosocomial infections might now be in the order of $5.5 billion. The problem of health-care-associated infection is more serious in some countries than others and there is considerable variation in its frequency between hospitals and other health-care organizations within countries.

Recent baseline studies of the prevalence of medical errors or adverse events have been referred to. It could be argued that there is no further need for such studies given that several authoritative publications have now identified the size of the problem within a range of prevalence estimates. There are two important reasons for continuing with such studies. Firstly, they have been shown to provide the mandate and commitment for action on patient safety within a country and a health-care system. Although policymakers or practitioners can stay within a “comfort zone” if studies have been undertaken elsewhere, they cannot do so if a valid study shows that their system shares in the problem. Secondly, there has been much less work to establish the scale and the nature of patient safety problems in developing countries especially like ours.

Definitions and Context

The lack of standardized nomenclature and a universal taxonomy for medical errors complicates the development of a response to the issues outlined in the IOM report. A number of definitions have been applied to medical errors and patient safety. In "*To Err is Human"*, the IOM[5] adopted the following definition:

> *"An error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim."*

In an effort to thoroughly consider all of the relevant issues related to medical errors, the IOM definition was expanded, as follows:

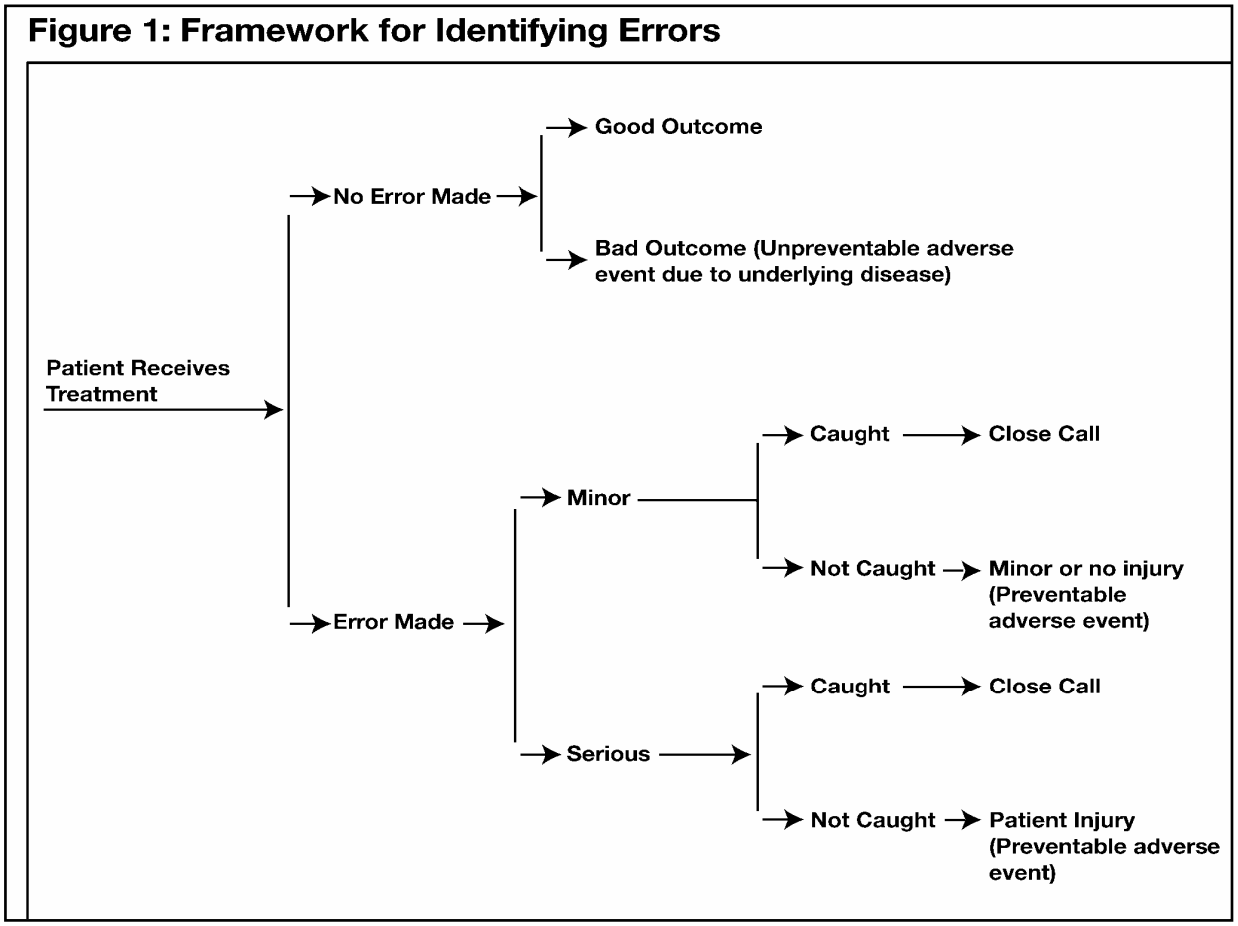
"*An error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures, and systems*."

"*An adverse event is an injury caused by medical management rather than the underlying condition of the patient. An adverse event attributable to error is a "preventable adverse event." Negligent adverse events represent a subset of preventable adverse events that satisfy legal criteria used in determining negligence (i.e., whether the care provided failed to meet the standard of care reasonably expected of an average physician qualified to take care of the patient in question)"* [5]

It is critical to recognize that not all bad outcomes for patients are due to medical errors. Patients may not be cured of their disease or disability despite the fact that they are provided the very best of care. Additionally, not all adverse events that are the result

of medical care are, in fact, errors. An adverse event is defined broadly as an injury that was caused by medical management and that resulted in measurable disability (Leape, 1991). Some adverse events, termed "unpreventable adverse events," result from a complication that cannot be prevented given the current state of knowledge. Many drugs, even when used appropriately, have a chance of side effects, such as nausea from an antibiotic. The occurrence of nausea would be an adverse event, but it would not be considered a medical error to have given the antibiotic if the patient had an infection that was expected to respond to the chosen antibiotic. Medical errors are adverse events that are preventable with our current state of medical knowledge.

Figure 1: Framework for Identifying Errors



Patient Safety:

Patient safety is freedom from accidental injury. At first glance, this may seem easy to pin down and manage. In the complex world of healthcare, though, patient safety is a moving target. It is a continuously emerging property of a complex system, a complex system involving people, processes, patients, families, and the technology that makes up the system. In order to understand how to guide an organization towards improving patient safety we must take into account this dynamic property of patient safety. It means that organizations must be in a continuous state of alert for patient safety.

Taxonomy for patient safety

Medicine continues to make efforts to move away from viewing medical error as an individual's responsibility and towards recognizing safety as a system property. Discussions about the taxonomy of patient safety and medical error reflect this change.

Patient Safety: freedom from accidental injury.

Adverse Event: an event or omission arising during clinical care and causing physical or psychological injury to a patient.

Preventable Adverse Event: a subset of adverse events that are judged to be preventable if appropriate and reasonable steps had been taken.

A Near Miss: A health care near miss is a situation in which an event or omission, or a sequence of events or omissions, arising during clinical care fails to develop further, whether or not as a result of compensating action, thus preventing injury to a patient.

Adverse events and near misses are the fundamental outcomes of patient safety. Adverse events, though, are only the visible tip of the iceberg in patient safety. The cause or causes of preventable adverse events almost always lie with failures that are deeper within a system of care that includes technical, organizational and human factors. .

The literature from the developing countries is very few and it is based on mostly routinely collected or existing information, which was very low and assessments were invariably carried out in tertiary hospitals. The implementation of reporting systems in developing countries seems to be both rare and unevenly distributed: all reported studies were from India or Pakistan. Finally, almost all the studies specifically considered adverse drug events. Although researchers regularly publish studies of medical error, adequate epidemiological information is limited to a few institutions, procedures, and specialties. Because most studies were conducted in academic referral centres the results may not be generalisable to community based hospitals and outpatient care facilities.

Comparing studies[30] is difficult because research methods are not standardized. The lack of agreement about methods and the variable rigour of their application contribute to the variations found in error rates. There is a serious need for researchers to use consistent definitions and methods and for collaborative work on measuring error. Systems for monitoring and reporting error could provide the platform from which more detailed studies of subpopulations could develop. However, expecting that individuals will carry out health care flawlessly creates an environment in which clinicians are reluctant to report their errors. Universal underreporting, in turn, undermines the ability to measure error accurately.

For these reasons the precise prevalence and magnitude of medical error is unknown, but it is probably enormous. We are aware of no study showing that medical care can be provided without error. In fact, the more closely we examine patient care, the more error we find. No setting is free from hazards and no specialty is immune, and patients are at risk no matter what their age, sex, or health status.

But the risk is not homogeneous. Patients who are sicker, subjected to multiple interventions, and who remain in hospital longer are more likely to suffer serious injury as a result of medical mistakes. Unless we make substantial changes in the organisation and delivery of health care, all patients particularly the most vulnerable will continue to bear the burden of medical error.

Studies using implicit review[30] to estimate the impact of medical errors on hospital deaths have been widely quoted and have generated national policy proposals and debate in the USA. Review of medical records is sometimes referred to as the "benchmark for estimating the extent of medical injuries occurring in hospitals", especially as most current estimates are based on this method. The method, originally developed by the California Medical Association[26] in the late 1970s, was first used for epidemiological purposes in the Harvard Medical Practice Study, and since then has been used for almost all epidemiological studies in acute care institutions and in other settings.

Hence for the above mentioned reasons to make a start in identifying where we stand in our country this study was done using In-patient mortality as an indicator of quality of care. In-patient mortality though not a good indicator might be a starting point for clinicians to assess systematically the circumstances of death of the patients.

AIMS

To study the profile of causes of deaths among hospitalizations in General Medical wards. To perform a systematic analysis of the recorded causes and classify possible medical error related deaths.

OBJECTIVES

The main objectives of the study are

1. To study the profile of causes of deaths among hospitalizations by the general medicine units.
2. To determine frequency of occurrence of medical error related deaths and factors contributing to it.

METHODS

Study design:

A one-year cross-sectional study.

Study setting:

The study was conducted during 1st January 2005 through 31st December 2005 in The Christian Medical College Vellore. In that year there were 68,872 hospitalizations and 1,758 deaths were recorded. In the wards under general medicine units there were 6130 hospitalizations and among them 496 deaths.

Study subjects:

All 496 deaths occurring in the medical wards and the medical ICU were included.

Study materials:

Data on all in-hospital deaths such as diagnosis, elective or emergency hospitalization, duration of stay in hospital prior to death and details as mentioned in annexure 1(enclosed) were collected. The cause of death as recorded by the treating senior house officer/post graduate physician/intensivist trainee and verified by the supervising physician was noted. The cause of death is as defined by the International WHO death certificate form as the "underlying disease eventually leading to death". The immediate cause of death is the "disorder precipitating death". The diagnosis was coded based on system involved using the International Classification of Diseases-10 (ICD-10 WHO 2000). The deaths were categorized based on the following definitions:

I) Natural or Unnatural deaths:

i) Natural deaths are deaths that occur due to the underlying disease process.

ii) Unnatural deaths are deaths that occur due to unnatural causes like homicides, suicides, assaults, accidents.

II) Expected or Unexpected deaths[15]:

A death is considered "Expected", if there is a written 'Do Not Resuscitate' (DNR) order or if the patient had been admitted for palliative terminal care as documented in the chart. A death is considered "Unexpected", if there is no written DNR order or, death occurred in the patient who had been hospitalized for the purpose of receiving appropriate therapy with a terminal event occurring from which the patient could not be resuscitated. The appropriateness of the medical care and therapy for acute deterioration was assessed by bedside physiological and laboratory parameters. The table lists the abnormal values for bedside and laboratory parameters.

Table 2: Abnormal Bedside and laboratory values[14]

Bedside Physiological parameters	Laboratory parameters	
	Biochemical	Hematological
BP systolic < 100 mm Hg or > 200 mm Hg Pulse rate < 60/mt or > 120/mt Temperature < 35.5^0C or > 38.5^0C Respiratory rate < 10 breath/mt or > 25 breaths/mt Urinary output < 200ml / 12hours O_2 saturation < 90%, Glasgow coma scale < 12	Creatinine > 1.5 mg/dL Sodium < 130meq/L or > 150 meq/L Potassium <3.0 meq/L or > 6meq/L Pao_2 < 70 mm Hg $Paco_2$ > 45 mm Hg Arterial standard base excess > ± 4 mmol/L	White cell count >20,000cells/mm^3 or < 2000cells/mm^3 Hemoglobin < 9g/dL Platelet count < 50,000/ mm^3 International Normalised Ratio > 2.5

The process of patient care was reviewed for the appropriateness of care immediately prior to the deaths and classified as:

III) Optimal or Sub-optimal care[14].

Optimal care is defined as identification and correction of any abnormal bedside or laboratory recordings within 12 hours by initiation of appropriate medical care and therapy. Despite optimal care being provided if the abnormal parameter persisted or death occurred then it is considered due to the natural history of the disease.

Sub-optimal care is defined as identification of abnormal bedside or laboratory recordings with inappropriate or inadequate medical care and therapy or non-identification of abnormal bedside or laboratory recordings.

These deaths with sub-optimal care were considered as likely medical errors. The medical errors[5] were classified as

i) Judgmental errors are therapy related errors. E.g. like not initiating appropriate therapy, not using DVT prophylaxis

ii) Vigilance errors are monitoring lapses.

iii) Technical errors are complications due to procedures and products-equipments malfunction.

iv) Medication errors: E.g. adverse drug reactions, anaphylaxis and other drug related complications.

v) System errors: E.g. nosocomial infection, pressure sores infection, aspiration pneumonias.

STATISTICAL METHODS:

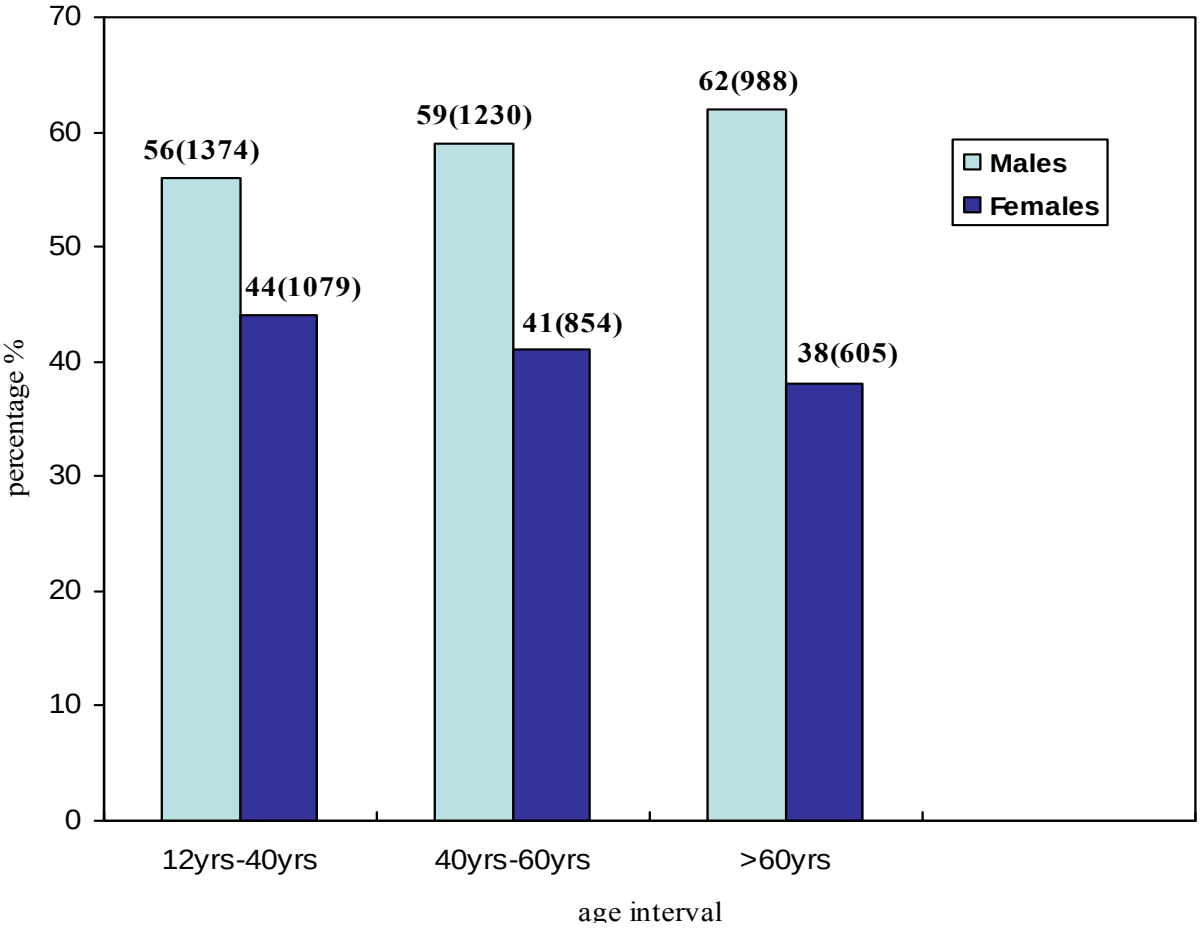
The data as collected on the proforma were typed into Excel version 11 of MS-Office 2003 to build the database and was analysed using SPSS version 13.0. The test of significance was done using Pearson's $\chi 2$ test for non-parametric variables and T-test for parametric variables.

RESULTS & ANALYSIS

ADMISSION PROFILE:

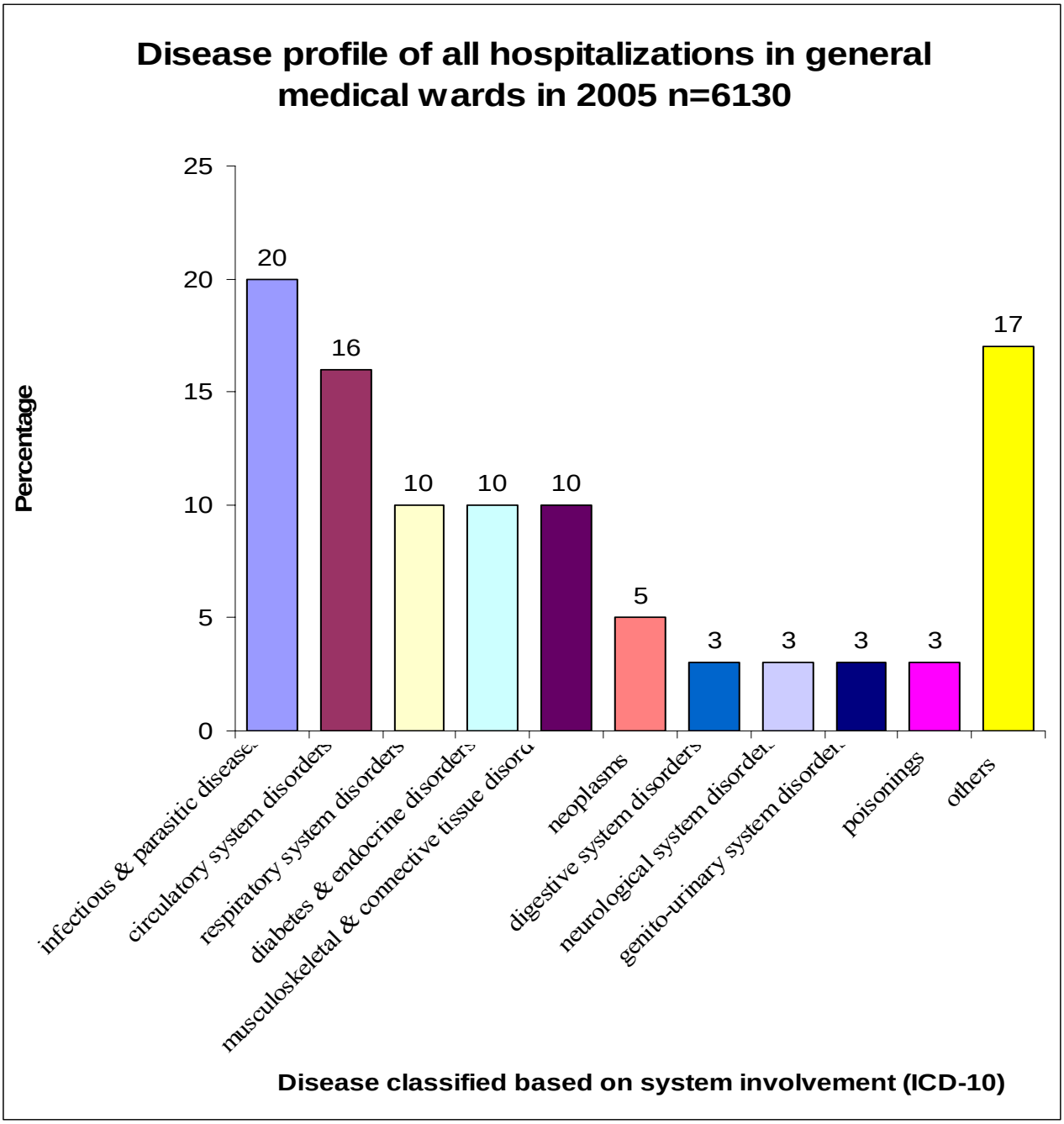
There were 6130 admissions in General medicine during the period January 1st through December 31st 2005

Figure 2: **Age Vs sex distribution of all admissions in general medical wards in 2005 (n =6130)**



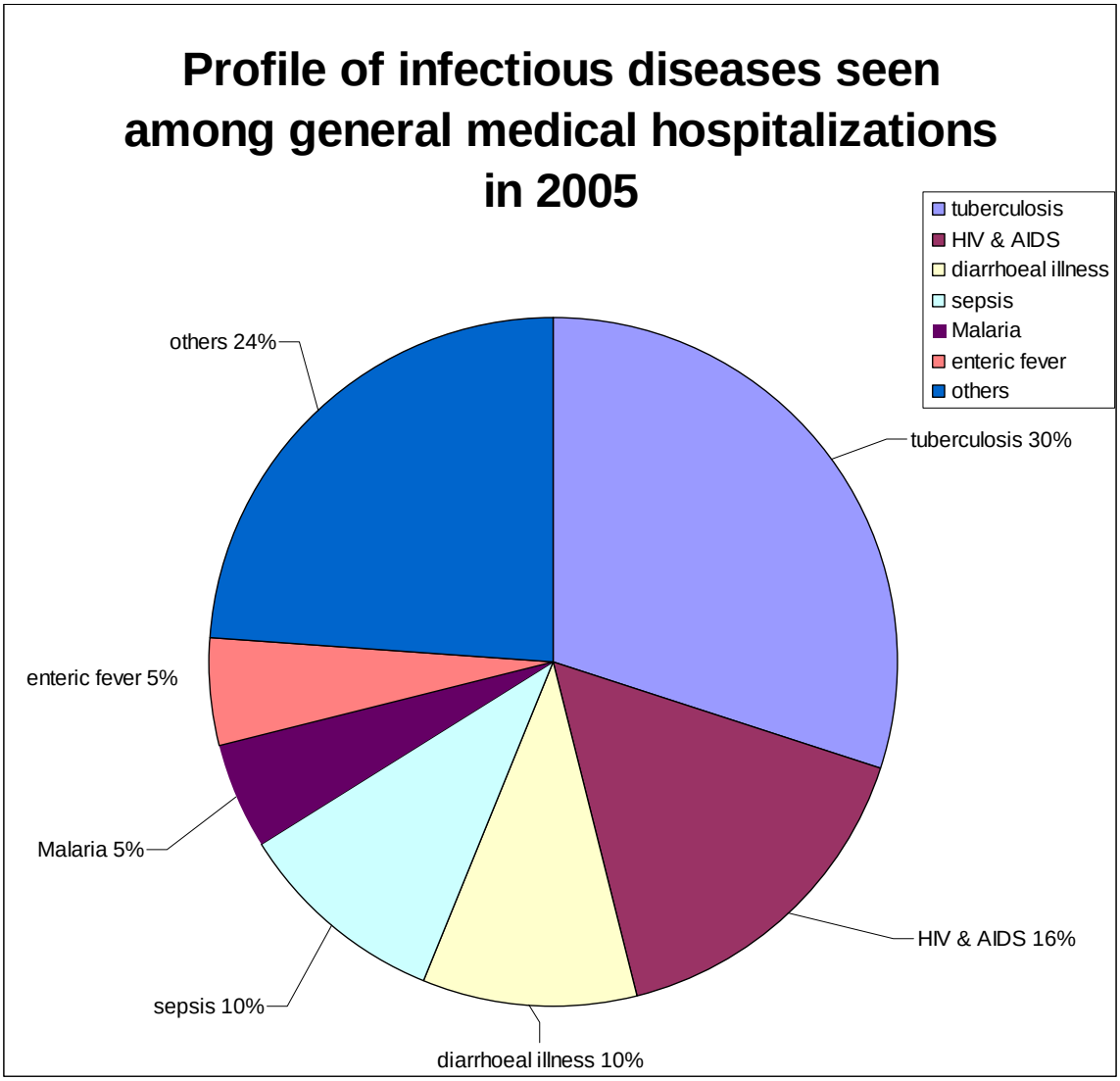
The Male: Female ratio among all admissions in the general medical wards in 2005 was **6: 4. There** were more male patients than female patients in all age groups this difference is statistically significant **(*p* = 0.001)**

Figure 3:



The others include diseases involving nutritional and metabolic diseases, Mental and behaviour disorders, skin and sub-cutaneous tissue diseases, blood and blood forming organs and certain disorders involving immune mechanisms, congenital malformations, deformations and chromosomal abnormalities.

Figure 4:



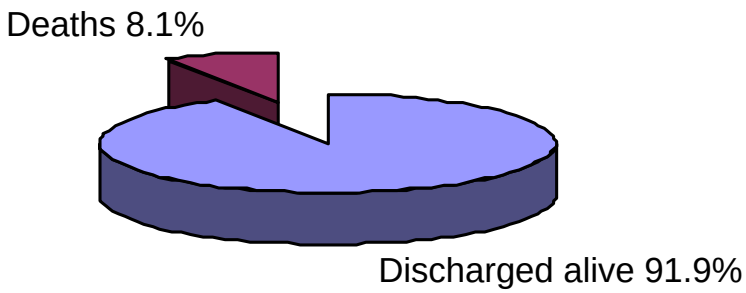
The others include diseases like Rickettsial infections, leptospirosis, Staphylococcus and Streptococcus infections, dengue fever, undifferentiated acute febrile illnesses etc. Tuberculosis is the leading cause among infection at 30% followed by HIV and AIDS related diseases excluding tuberculosis at 16%

DEATH PROFILE:

In 2005 there were 68,872 hospitalizations and 1758 deaths overall in the hospital. The death rate was at 2.6%

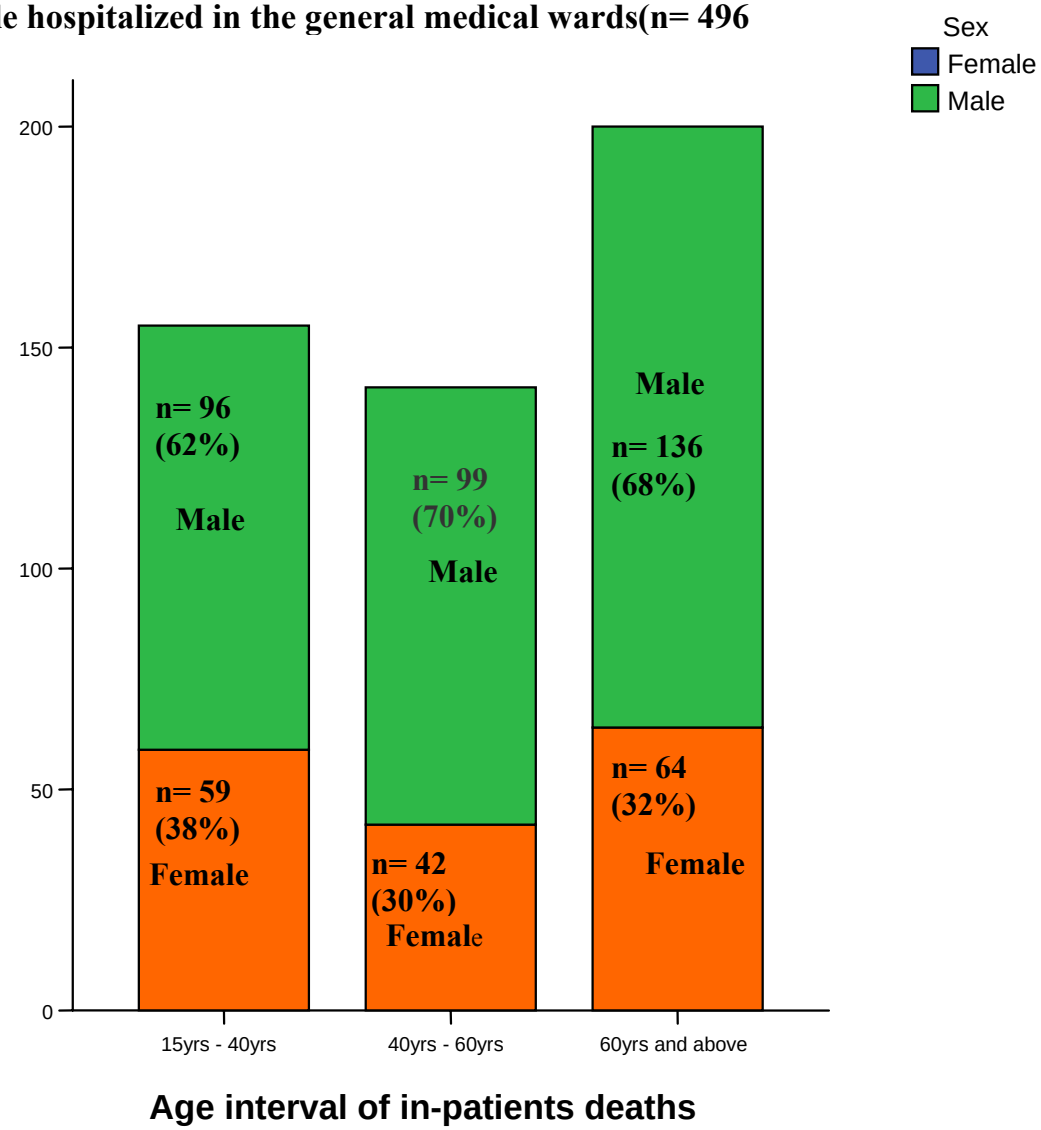
Figure 5:

Proportion of deaths that occurred during hospitalizations in general medical wards (n=496deaths/6130 admissions)



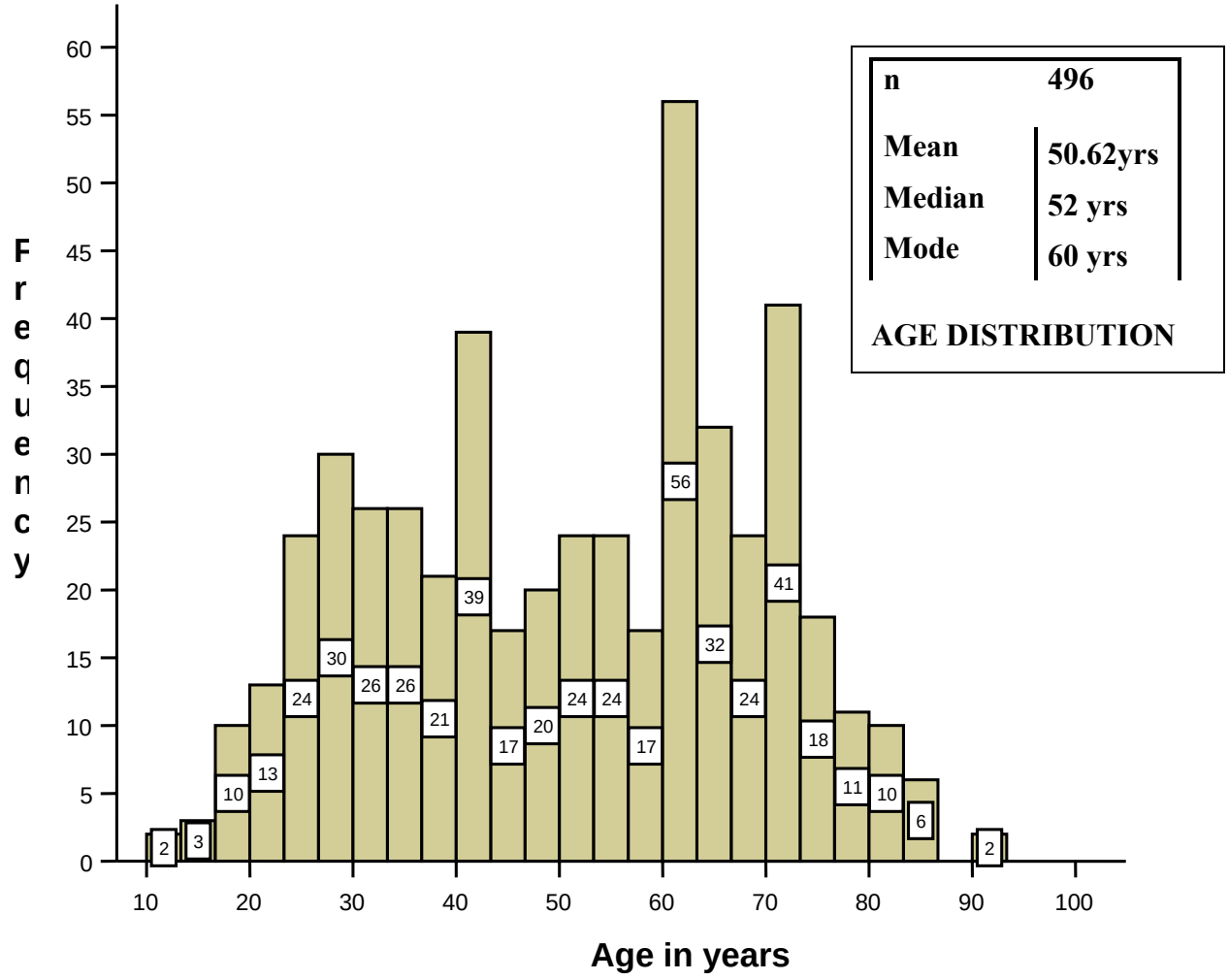
The death rate in the year 2005 among all admissions in general medicine wards was 8.1%.

Figure 6: **Age and sex distribution of patients who died while hospitalized in the general medical wards(n= 496**



The correlation between age and sex among the in-patient deaths in the general medical wards was analysed and was not statistically significant (***p= 0.28, 0.28, 0.26).***

Figure 7: AGE DISTRIBUTION OF ALL DEATHS IN MEDICAL WARDS IN 2005



The median age of patients who die in the general medical wards was 52 years with the mode at 60 years. The range was between 13 years to 93 years.

Type of Admission:

The Manner in which patients were admitted was on an emergency basis via the casualty or on an elective basis via the Out-Patient Department.

Figure 8: Type of admission: Elective Vs Emergency (n =496)

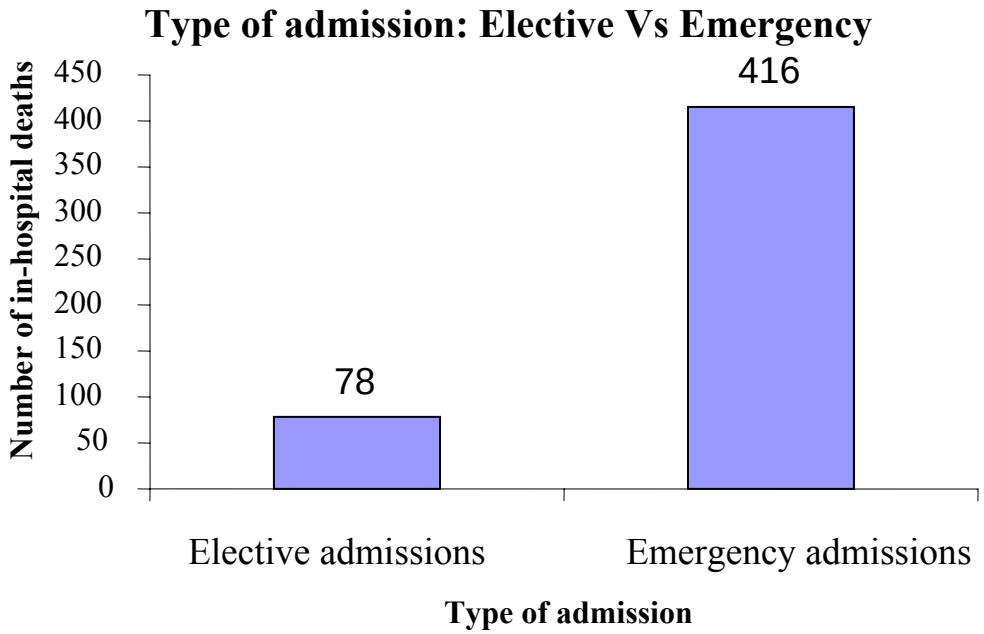
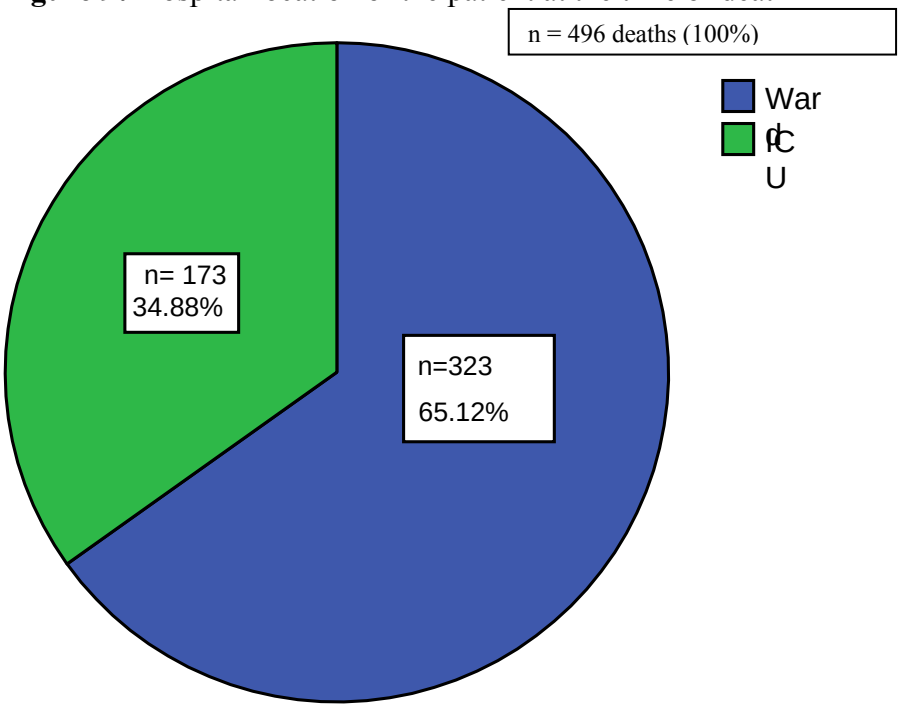


Figure 9: Hospital location of the patient at the time of death

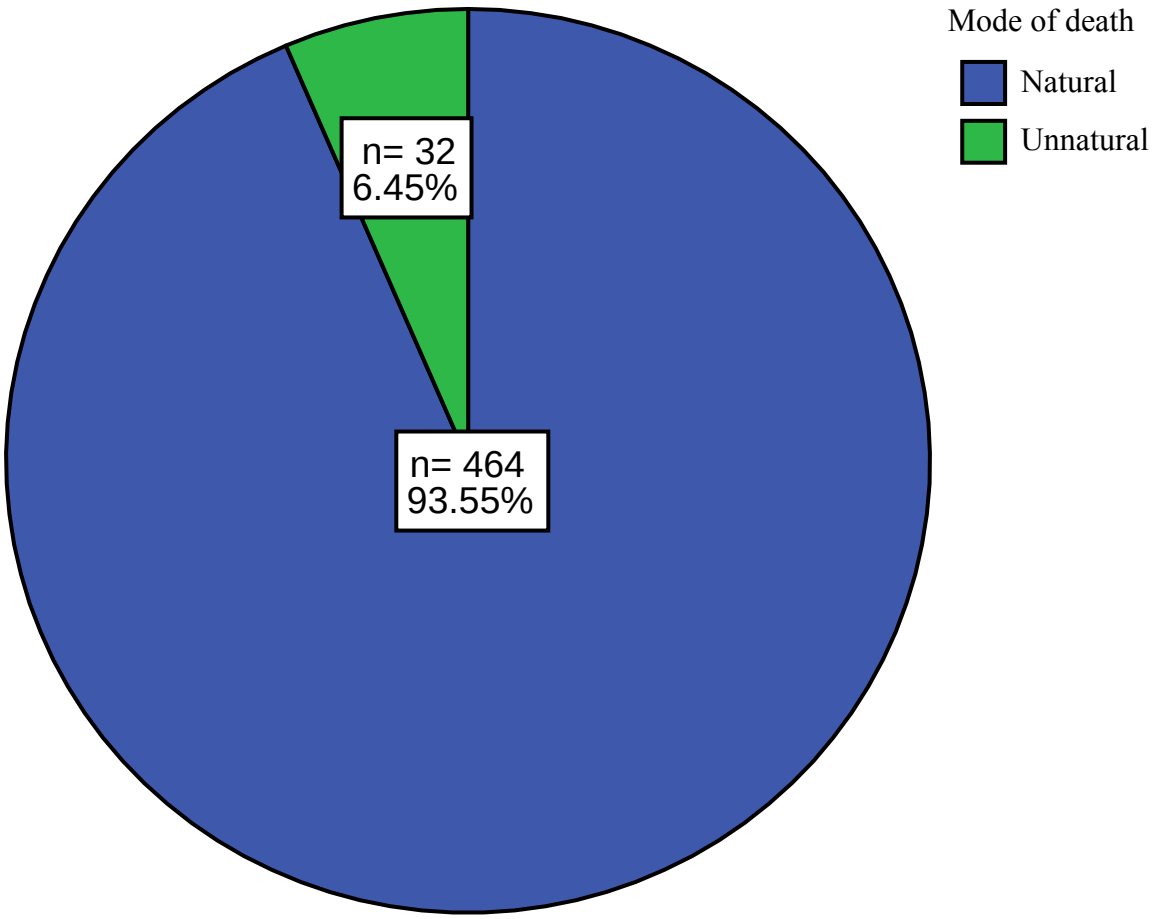


There were 702 admissions and 173 deaths in ICU(25%).

Mode of death:

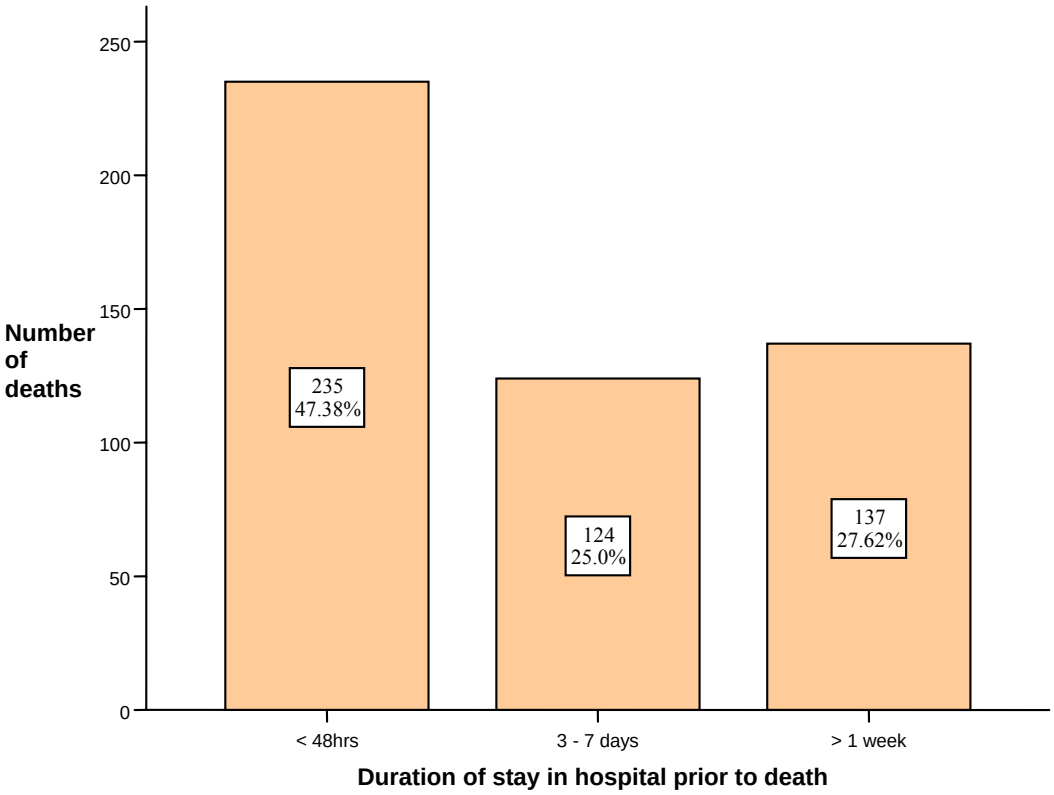
Unnatural cause of deaths accounted for 6.5% of deaths in the medical wards

Figure 10: **Mode of death (n= 496)**



There were 32 unnatural deaths among 496 deaths. All these unnatural deaths were due to suicidal attempts requiring hospitalization.

Figure 11: The Duration of stay in hospital prior to death



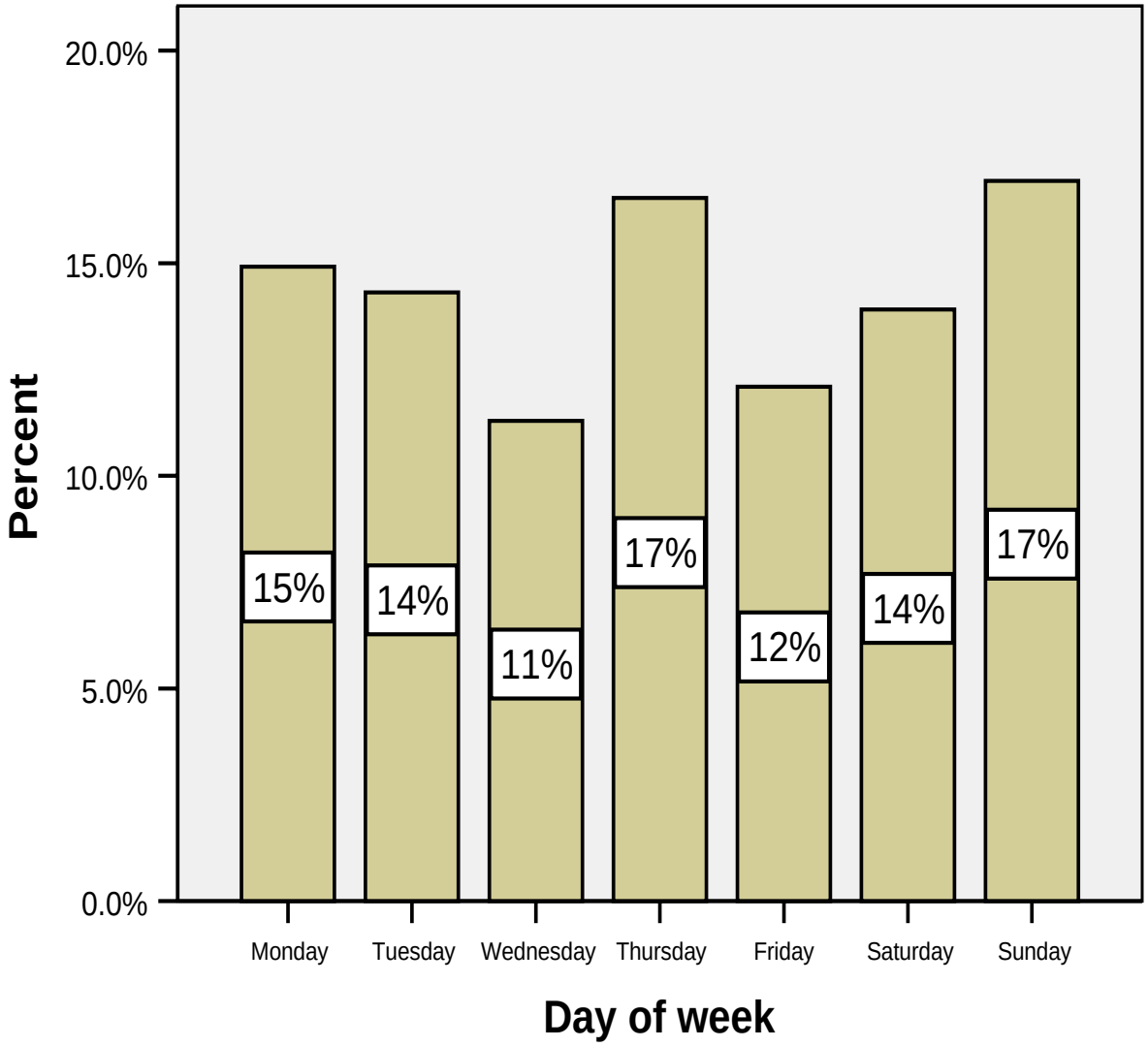
Time of Death:

The time of occurrence of the deaths was taken according to the work shifts of the nursing staff.

Table 3: Time of occurrence of death

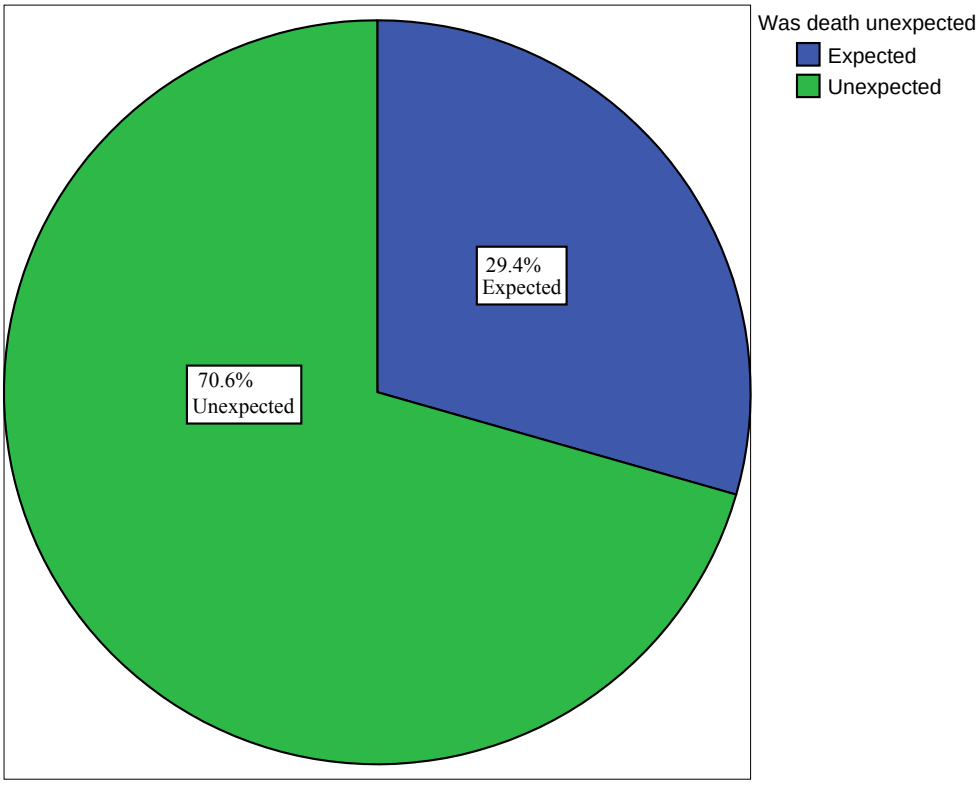
Time Shift	Frequency	%
7:00am - 4:00pm(morning shift)	196	39.5
4:00pm - 10:00pm(bridge shift)	123	24.8
10:00pm - 7:00am(night shift)	177	35.7
Total	496	100.0

Figure 12: Deaths occurring on days of the week n = 496



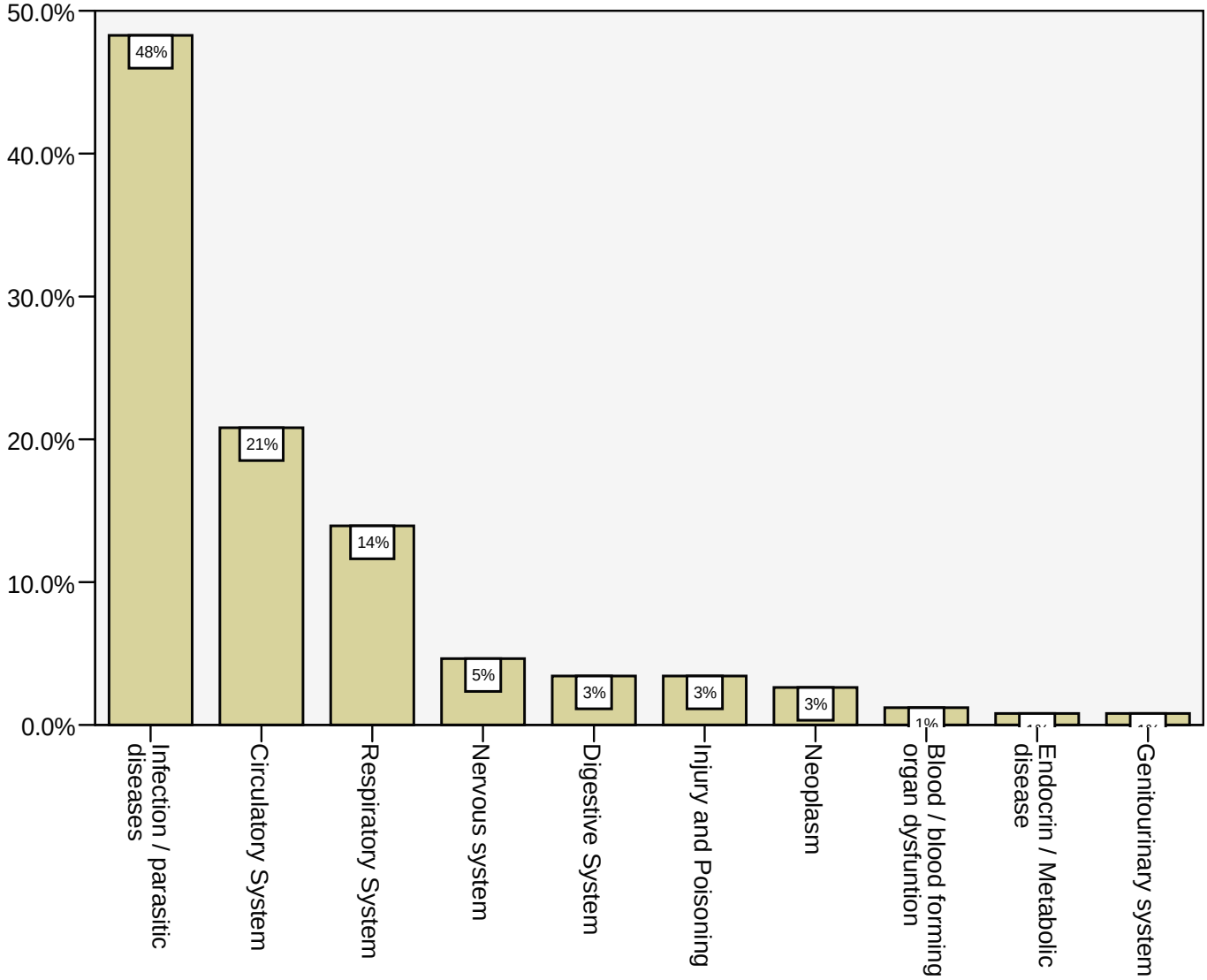
There was no significant difference among deaths occurring on different days of the weeks.

Figure 13: Percentage of Expected Vs Unexpected deaths (n = 496 deaths)



There were 143 patients with written DNR orders at the time of admission or during their course of stay in the hospital. Among these 143 expected deaths (29.4%) there were 9 patients admitted for palliative care having malignancies in the terminal stages.

Figure 14: **Underlying cause of death (n =496, 100%)**



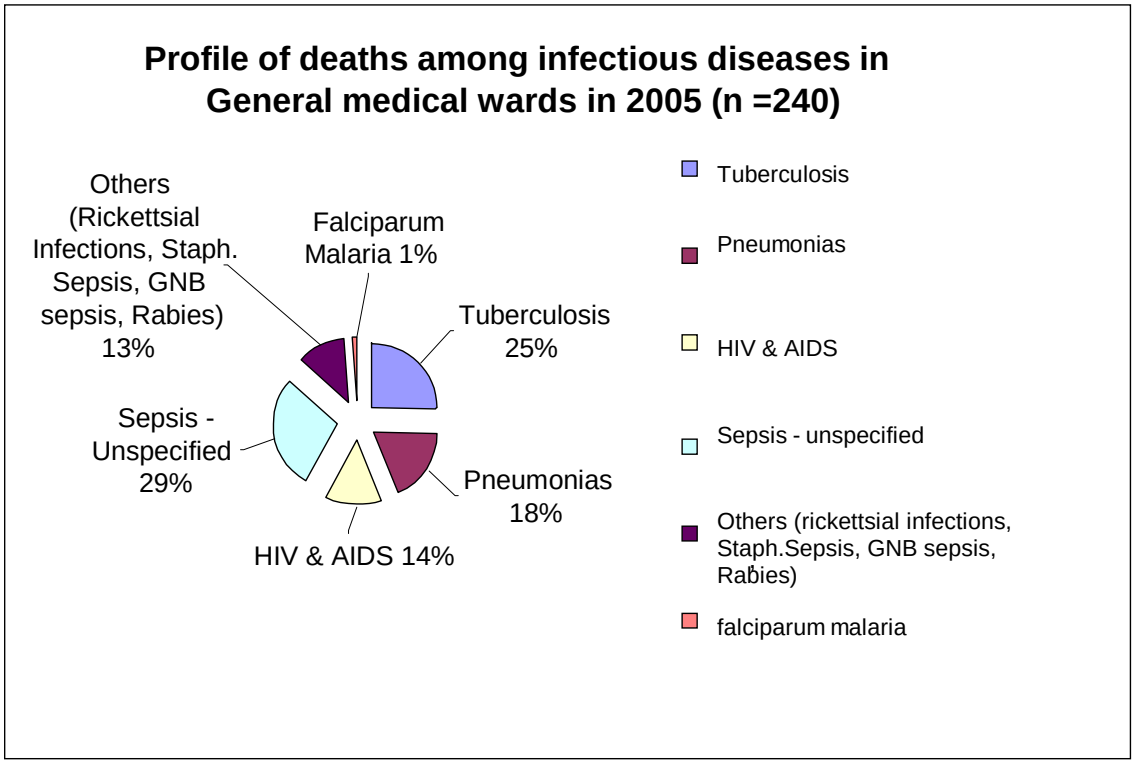
DISEASE CODED BASED ON ICD-10 SYSTEM INVOLVEMENT

Table 4: Underlying cause of deaths

ICD-10 CODE	SYSTEM INVOLVEMENT	n = 496 (100 %)
I	Infection / parasitic diseases	239 (48)
II	Neoplasm	13 (3)
III	Blood / blood forming organ dysfunction	6 (1)
IV	Endocrine / Metabolic disease	4 (1)
VI	Nervous system	23 (5)
IX	Circulatory System	103 (21)
X	Respiratory System	69 (14)
XI	Digestive System	17 (3)
XIV	Genitourinary system	4 (1)
XX	Injury and Poisoning	17 (3)
	Total	496 (100.0)

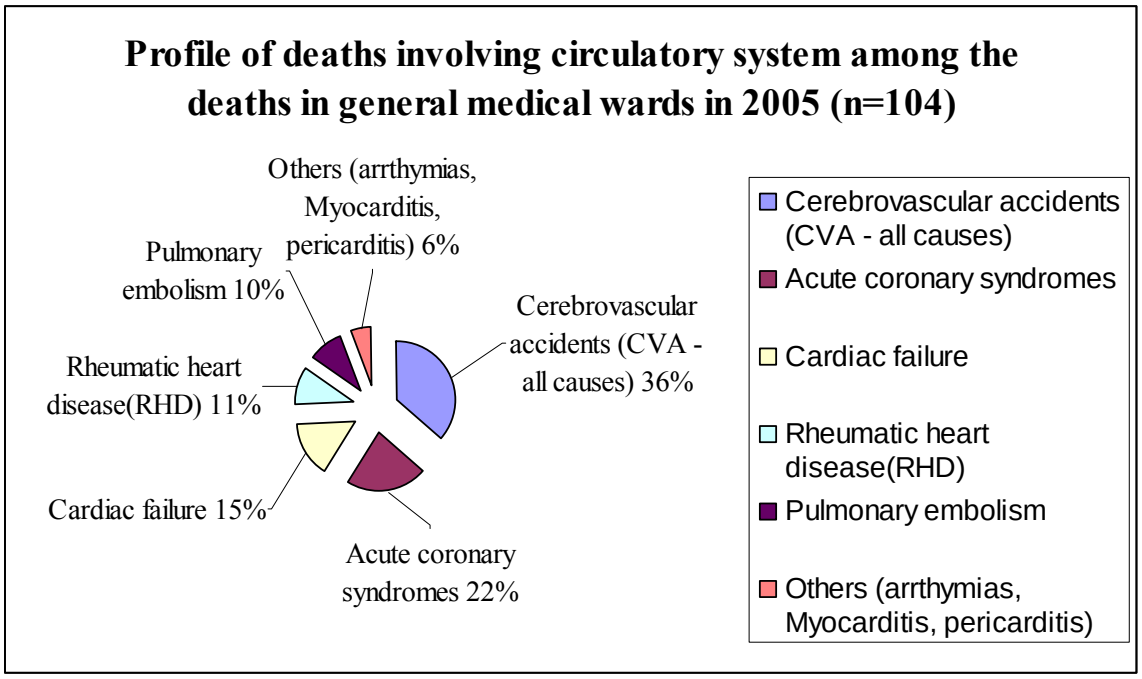
There were no deaths classifiable to codes V (Mental and behavioural disorders), VII (Diseases of the eye and Adenexa), VIII (diseases of the ear and mastoid process) , XII (Diseases of the skin and subcutaneous tissue), XIII (Diseases of the musculoskeletal system and connective tissue), XV – XIX (Pregnancy, childbirth and the puerperium, Certain conditions originating in the perinatal period, Congenital malformations, deformations and chromosomal abnormalities, Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified, Injury and certain other consequences of external causes) among the underlying causes for the 496 deaths.

Figure 15:



There were a total of 1226 patients hospitalized with infectious diseases with 240 deaths among them showing that 19.5% of patients admitted with infectious diseases die.

Figure 16:



Among 984 hospitalizations due to circulatory system disorders there were 104 deaths (10.4%).

Medical errors leading to Death:

There were 56 deaths (11.3%) due to medical errors out of 496 deaths.

Figure 17: Medical error related deaths n = 56

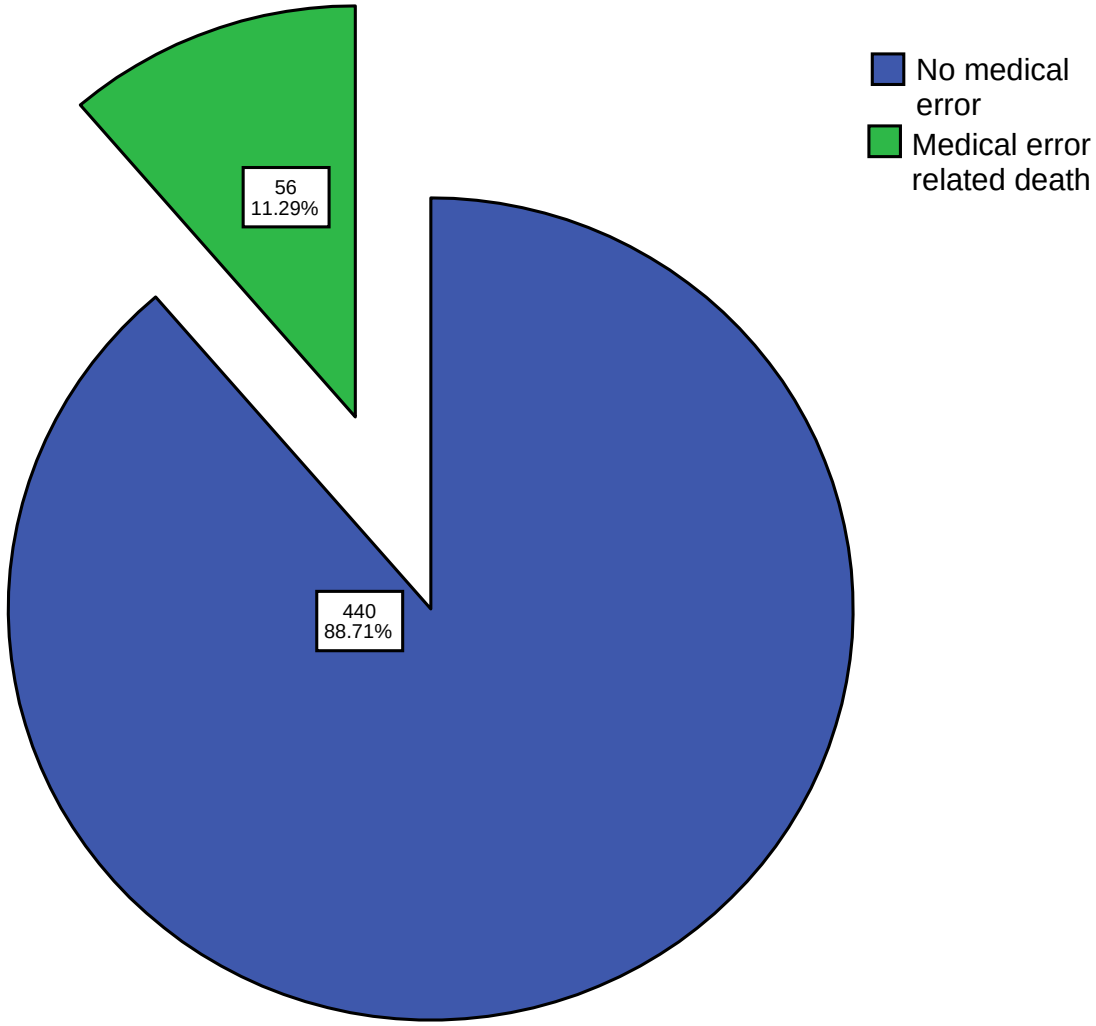
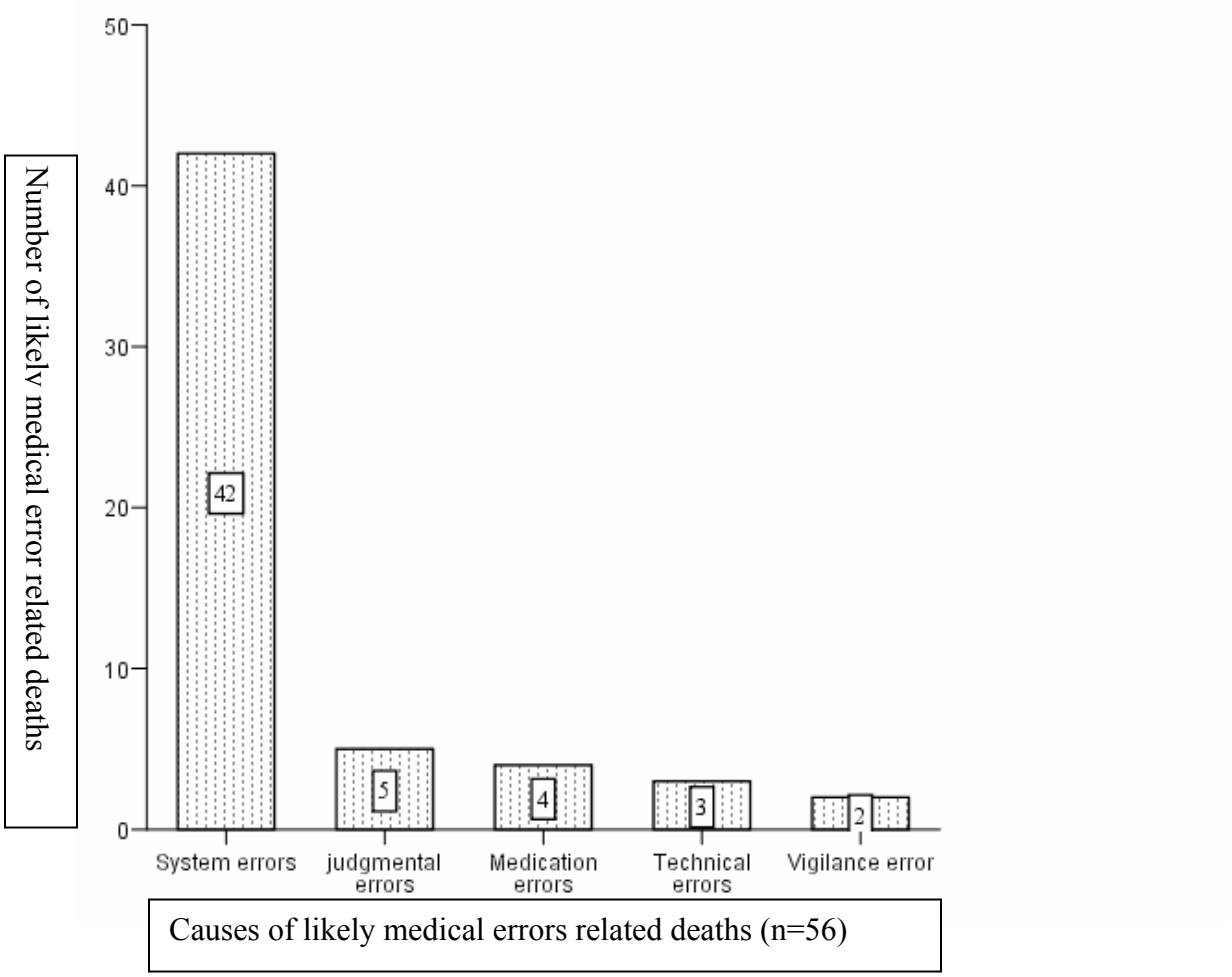


Figure18: Causes of medical errors leading to death (N=56)



Likely System errors (n=42, 75%):

There were 17 cases each of ventilator associated pneumonia and aspiration pneumonia.

Seven cases of nosocomial Urinary Tract Infection (UTI)

One case of infected pressure sore.

Likely Judgemental errors (n=5, 9%):

Two cases of Deep Venous Thrombo-embolism (DVT) not on adequate anti-coagulation developed pulmonary embolism.

One case of DVT wrongly treated as Cellulitis with antibiotics instead of anti-coagulation developed pulmonary embolism.

One case of large anterior wall myocardial infarction with Left Ventricular thrombus not on anti-coagulation developed pulmonary embolism.

One case of systemic vasulitis with Cushing's syndrome and also bedridden developed pulmonary embolism because DVT prophylaxis not given

Likely Medication errors (n=4, 7%):

Two cases of Toxic epidermal necrolysis due to drug therapy

One case of Category-I Anti-Tuberculous therapy was started for a patient with hepatic dysfunction who then developed hepatic encephalopathy.

One case of anaphylaxis to diclofenac injection

Likely Technical errors (n=3, 5%):

One case of ventilator malfunction

One case of post-tracheostomy bleeding

One case of Ventriculo-peritoneal shunt malfunction

Likely Vigilance errors (n=2, 4%):

One case after transfer from ICU to the ward was not monitored properly.

One case after admission from casualty to the ward was not monitored properly.

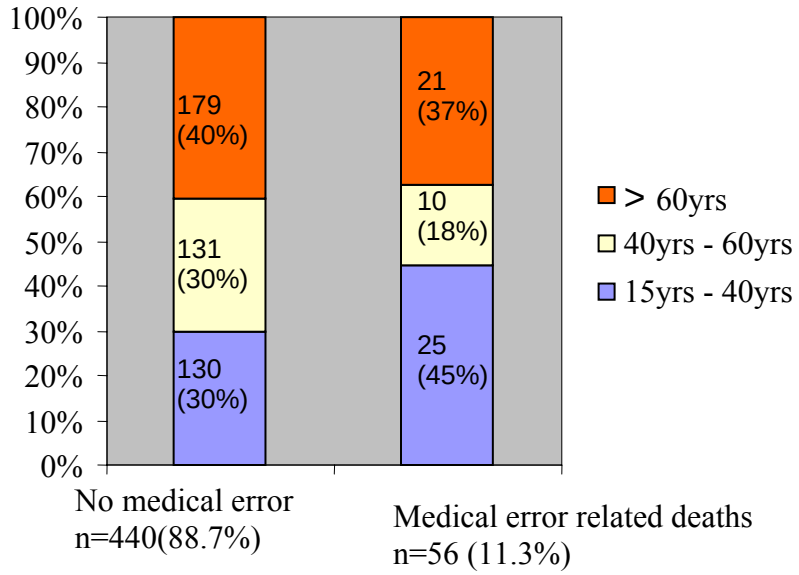
Both the cases had inadequate records and very less documentation.

Preventable deaths due to medical errors:

Based on these baseline characteristics further analysis was done to look for any significant associations between Medical errors related deaths with various factors like

1. Age of the patient (Figure 19)
2. Gender of the patient
3. Type of admission
4. Time of occurrence of death (Table 5)
5. location of patient at the time of death (Table 6, 7)
6. Duration of stay in hospital prior to death (Figure 21)
7. Mode of death (Table 8)
8. Among unexpected deaths (Table 9)
9. Underlying Patient /hospital/environmental factors (Table 10)

Figure 19: Age Vs Death related to medical errors (n=496)



The younger age groups (12yrs - 40yrs) had more deaths classified as due to medical error ***p value of 0.044***.

Among females 14.5 %(n=24) of the deaths were due to medical errors as compared to 9.7 %(n=32) among males. The difference was not statistically significant (p =0.073)

Among elective admissions 78 patients died and among them 7(9%) deaths are due to medical errors. Among emergency admissions 416 patients died and in them 49(11.8%) deaths are due to medical errors. The difference was not statistically significant (p =0.31)

Among 56 medical error related deaths 19(11.5%) occurred in morning shift (7am-4pm), 12(9.9%) in bridge shift (4pm-10pm) and 25(11.9%) in night shift (10pm-7am). The difference was not statistically significant (p =0.82)

Table 5: Day of week Vs Medical error related deaths (n =56/440)

Day of week	No Medical error	Medical error related deaths
Monday	66(15%)	8(14%)
Tuesday	63(14%)	7(13%)
Wednesday	49(11%)	7(13%)
Thursday	72(16%)	10(17%)
Friday	56(13%)	4(7%)
Saturday	57(13%)	13(23%)
Sunday	77(18%)	7(13%)
Total	440(100%)	56(100%)

There was no association between the day of the week and medical error related deaths. 23% of medical error related deaths occurs on a Saturday. But this is not statistically significant (p =0.266)

Table 6: Location of the patient at the time of death Vs Medical error related death

Location of patient at the time of death	No Medical error n=440	Medical error related death n=56
Ward	289(89.5%)	34(10.5%)
ICU	151(87.3%)	22(12.7%)
Total	440(88.7%)	56(11.3%)

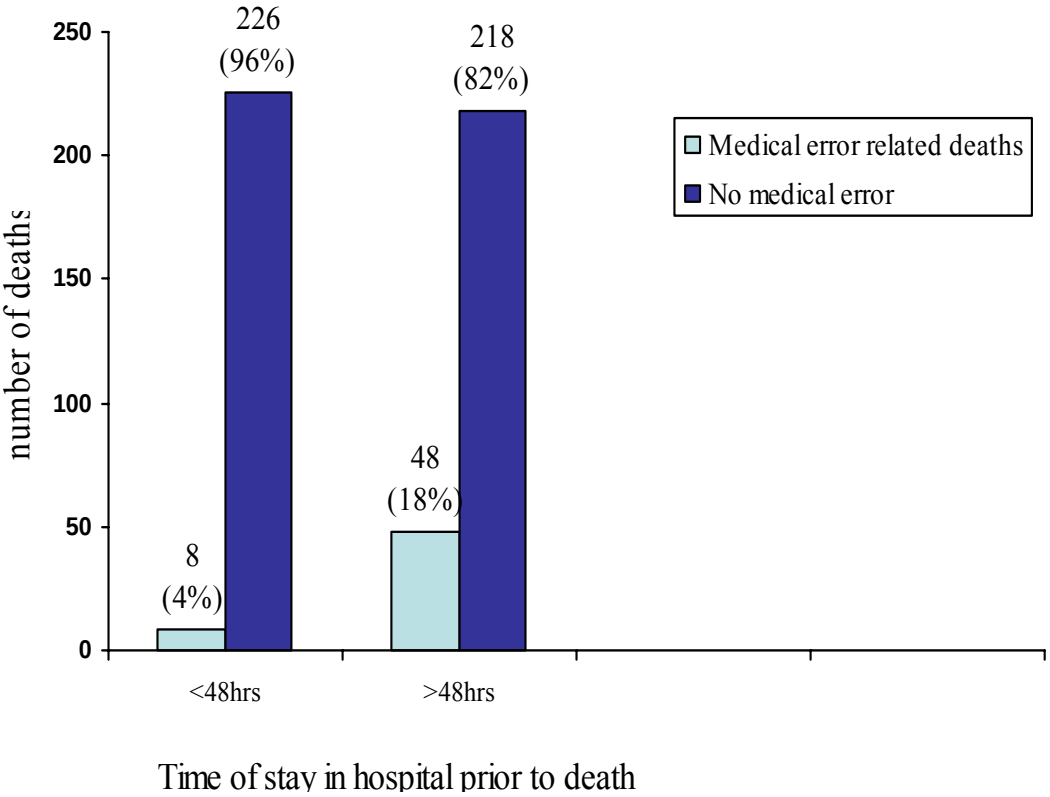
The location of the patient at the time of death is analysed against medical error related deaths and it is found that there were more adverse event related deaths occurring in the ICU than the wards with regards to the percentages but is not statistically significant (p =0.277)

Table 7: Medical error related deaths Vs location of patient at the time of death

Cause of Medical error	ward	ICU
System errors (Nosocomial infection, Pressure Sore Infection)	23(67%)	19(85%)
Judgmental errors (Embolism)	4(12%)	1(5%)
Medication errors (ADR/anaphylaxis)	3(9%)	1(5%)
Technical errors	2(6%)	1(5%)
Vigilance errors	2(6%)	0(0%)
Total (n=56)	34(100%)	22(100%)

The distribution of causes of medical error event related deaths with regards to the location of patient at the time of death i.e. in the ward/ICU has shown that the rates of nosocomial infections in ICU are higher with regards to the percentages though statistically not significant along with lesser numbers of technical errors, vigilance errors, embolism and pressure sore related complications in comparison with the ward.

Figure 21: Duration of stay in hospital prior to death Vs Medical error related deaths



The mean duration of stay in hospital for deaths not related to medical error was 5.9 days and in deaths related to medical error it was 10.6 days. The medical error related deaths increase as the duration of stay in hospital increases with a statistically significant ***p value of 0.001***.

Table 8: Natural/Unnatural deaths Vs Medical error related deaths

	No Medical error n=440	Medical error related deaths n=56 deaths
Deaths due to natural causes	417(89.9%)	47(10.1%)
Deaths due to unnatural causes(suicides)	23(71.9%)	9(28.1%)
Total	440(88.7%)	56(11.3%)

Deaths occurring due to unnatural causes had more chance of being complicated by a medical error as shown in table 10. It is statistically significant with a ***p value of 0.006***.

Table 9: **Unexpected deaths Vs Medical error related deaths**

Unexpected deaths	No Medical error n=440	Medical error related deaths n=56
No	138(94.5%)	8(5.5%)
Yes	302(86.3%)	48(**13.7%)**
Total	440(88.7%)	56(11.3%)

Among the unexpected deaths there were a significant number of Medical error related deaths as compared to expected deaths with a ***p value of 0.008.***

The various patient factors and the hospital factors were individually assessed for any influence on the adverse event related deaths and it is found that the presence of diabetes in the patients make them prone for adverse event related deaths but it was not statistically significant (p =0.102).

Table 10: Underlying psychiatric disorder Vs Medical error related deaths

Psychiatric disorder	No Medical error (n=440)	Medical error related deaths (n=56)
No	435(89.1%)	53(10.9%)
Yes	59(62.5%)	3**(37.5%)**
Total	440(88.7%)	56(11.3%)

Patients with underlying Psychiatric illnesses have a significant chance of having an adverse event related death with a ***p value of 0.05***.

The other underlying factors did not show any significant results.

DISCUSSION

ADMISSION PROFILE:

There were 6130 admissions in the year 2005 with a median age of 47 years and a mode of 65 years. The age distribution suggests that the majority of the admissions are in the young (12yrs - 40 yrs) and the elderly (>60yrs) populations with male predominance. Infectious diseases admissions account for majority of the admissions and among this group tuberculosis is the leading cause followed by HIV and AIDS related diseases (non tuberculous) and diarrhoeal diseases. This profile reflects the burden of infectious diseases in our country.[28]The second group involves the circulatory system disorders inclusive of cerebrovascular accidents. This is on par with the cause of death in the developed nations. Neoplasm or malignancy relates are only 5 % in this study while in the West it is the leading cause. The elderly[28] (>60yrs) presented with mostly non-communicable diseases like complications of hypertension, diabetes, malignancies. The younger (12yrs - 40 yrs) population[28] presented with tuberculosis, AIDS ands its opportunistic infections, suicidal attempts mostly with organophosphorus (OP) compounds. This disease profile also gives us an insight into the lifestyle changes that are happening with increasing incidence of non-communicable diseases and its complications.

DEATH PROFILE:

There were 496 deaths in 6130 admissions with a death rate of 8.09%. This rate was influenced by a number of factors like age, severity of principal diagnosis, types and complexity of co-morbidities, social and economic conditions of the patient and duration of stay in the hospital. In this study**,** In-hospital deaths had a median age of 52 years comparable with the general figures in India. In-hospital death is characterized by a higher proportion of men, 66.73% in this study. The deaths occurred in almost equal numbers in the elderly and the younger population groups. The profile of deaths in both the groups was different. In the elderly cerebrovascular accidents, chronic obstructive lung diseases were more common and in the younger population infectious diseases and suicidal attempts were more common.

More than 80% of the deaths occur among patients admitted on an emergency basis as compared to only 20% deaths admitted on an elective basis. The median duration of hospital stay was 3 days in this study with a range of 1 day to 91days. 35 % of the deaths occurred within the first 24 hours, 48% of all deaths by the second day and 72 % of the deaths by 1 week. First-day deaths are also called as early deaths constitute a significant portion of **a** hospital's mortality rate even though hospitals can do little to prevent them. Deaths occurring within the first 48hours in the hospital give us an idea of the moribund status of the patients at presentation. This maybe due to the reason that the hospital being a tertiary referral centre recieves patients after being treated elsewhere and after developing complications or late presentation due to lack of care and other financial reasons.

There were a total of 1226 patients hospitalized with infectious diseases with 240 deaths among them showing that 19.5% of patients admitted with infectious diseases die. Among 984 hospitalizations due to circulatory system disorders there were 104 deaths (10.4%). This shows that the patients present very late in their course of illness especially among the infectious diseases when they come in septic shock

6.45% of the deaths occurred due to unnatural causes. All of them were due to suicides in the community. This actually reflects the number of suicides that occur in the area catered to by the hospital. In this study "unexpected deaths" were 70% which is higher in comparison with western studies[15.] This may be due to the fact that there was more number of DNR orders or admission for palliative terminal care in the West as compared to our country where most patients are taken home for their terminal stages rather than be kept in the hospital.

MEDICAL ERROR RELATED DEATHS:

Among 496 deaths there were 56 deaths due to medical error accounting for 11.3 % of the deaths. Among the causes of medical error related deaths, system errors is the most common followed by judgmental errors, medication errors, technical errors and vigilance errors in the order of decreasing frequency[5].

Whenever an in-hospital death occurred suddenly or unexpectedly, there was a chance of it being due to medical error as suggested by a significant ***p value of 0.008.*** This is a consistent observation seen in earlier studies also[2, 3, 15].

Among Unnatural deaths there were a significant number of medical error related deaths (***p*=0.006).** This maybe due to the occurrence of system errors like nosocomial infections among these patients mostly ventilator associated pneumonias (VAP).

Medical error related deaths occurred in significant numbers among the younger age group in this study contrary to Western figures where the medical error related deaths occurred more in the elderly population. This maybe attributed to the reason that the majority of these deaths were due to ventilator associated pneumonia occurring among patients who were ventilated for treatment of Suicidal attempts and its complications(unnatural causes - OP poisoning) while in the Western population the medication related errors along with nosocomial infections occurred more among the elderly.

The medical errors related deaths were analysed with regards to the time of occurrence of the deaths. There is no statistical significance to the time of occurrence of death even though there is less staff at nighttime and weekends wherein monitoring lapses could occur and a similar analysis was done with regards to the day of the week and again no statistical significance was noted but numerically more deaths due to medical error occurred on Saturdays. Both the vigilance error due to monitoring lapses occurred on Saturday and Sunday suggesting that weekends need special attention with regards to possible lapses**.**

The duration of stay in the hospital prior to death and medical error related deaths were analysed and it showed that longer the hospitalization, higher the chance of developing medical error related death[15]. The mean duration of stay in hospital for deaths not related to medical error is 6 days and in deaths due to medical error is 11 days. Incidence of medical error related deaths increases as the duration of stay in hospital increases with the development of nosocomial infections with a significant p=0.001. This reflects the problem with the System - hospital infection control as most of the medical error related deaths are due to nosocomial infections. The proportion of deaths associated with hospital acquired septicaemia was reported in the literature to be as high as 30%[38]. The %age of nosocomial septicaemia observed in this study among the medical error related deaths is 42**%** which is much higher than all available data. This needs urgent action and there has been a number of changes initiated recently like hand hygiene campaigns and introduction of near patient alcohol rub, staff awareness sessions, improvement of ward cleaning routines, compulsory induction training for all staff, antibiotic guidelines for the hospital, increased surveillance and feedback of infection rates in the hospital. WHO and its partners launched the Global Patient Safety Challenge with the theme "Clean Care is Safer Care" in October 2005 and India is the first country of the south-east Asia to inaugurate the 'Clean Care is Safer Care' initiative and to sign the pledge committed to address health care associated infection.

The proportion of drug-related problems and of pressure sores seems to be underestimated in this study. Leape *et al.* report a proportion of 19% of drug-related problems among adverse events for hospitalized patients in acute care hospitals[15]. The in-

hospital mortality associated with pressure sores varies from 23% to 37% and rises to 50% when complicated by sepsis[5]. Therefore pressure sores are increasingly used as a marker of risk of death and of quality of care. Because of differences in the definition of complications of care in those studies, it is difficult to compare our results with those of other studies

The medical error related deaths in the hospital were analysed against various patient, hospital and environmental factors. The results suggested that most factors were not significantly associated with medical error related deaths. Patients with underlying Psychiatric illnesses had more chance of developing medical error related death probably because there was difficulty in assessing these patients' complaints. In this study the possibility of medical errors related to digitalis toxicity in rheumatic heart disease patients and medical error related deaths due to hyperkalemia in renal failure patients was looked for but surprisingly there were none. These findings suggest that either there were no monitoring lapses or the care was good.

The other major issue is performing an autopsy, which is less than 4% of the deaths and if this is improved upon then one gets a chance to review the deaths which occur unexpectedly and identify the problem involved in it. This low rate of autopsy is seen in other countries also and maybe attributed to prevailing cultural beliefs[16] or maybe due to reluctance of the attending physician to ask for the same.

This study has given us the insight into the level of medical errors which can lead to death. It has shown that the main areas that need attention are in the prevention of hospital related infections like:

i) Comply with current hand hygiene guidelines.

ii) Manage as sentinel events all identified cases of unanticipated death or major permanent loss of function associated with a health care-acquired infection.

There is a need to develop a reporting system by which one can keep track of all the errors especially medication errors and improve on it. A more theoretically informed and longitudinal approach might be to address the genesis of medical thinking about error through reforms to the aspects of medical education and professional socialization that help to create and perpetuate the existence of avoidable error, and reinforce medical collusion of error. Further changes in the curriculum, to emphasize team working, communication skills, evidence-based practice and strategies for managing uncertainty, are therefore potentially key components in helping tomorrow's doctors to discuss and cope with medical errors and to commit fewer of them. Given the complexity of hospital care, in the foreseeable future this kind of review may be the best source of estimating the overall impact of errors.

LIMITATIONS

i) The cause of death is ascertained from the death certificate but the death certificate maybe filled wrongly or inadequately. The sensitivity of the death certificate to detect the cause of death is only 57 **%**(ranging from 28% - 90%). [33]

ii) Difficulty to judge iatrogenic and preventable nature of medical error related deaths on the basis of occasional piecemeal data as many errors may not be actually documented in the medical record or identifiable by chart review[27].

iii) Underestimation of medical errors due to reluctance to second-guess the care of fellow clinicians[31], and overestimation of medical errors related deaths due to hindsight bias. Unlike the clinicians who cared for these patients, when reviewing the charts there is this advantage of knowing the final diagnoses and outcomes[31]. This may have influenced consciously or subconsciously resulting in second-guessing reasonable decisions and thereby inflating the true merits of alternative choices and decisions[27].

iv) There are other reasons to be cautious in interpreting this study's results. This hospital cannot be assumed to be representative of Indian hospitals in general. If this hospital cared for sicker patients or had better-than-average quality and patient care, the number of preventable deaths could have been underestimated although the overall mortality rates and the preventable death rate estimates are very similar to those in previous studies. One must be very cautious in making causal assertions from this review as currently available instruments to adjust for

severity of illness are not adequate to assess the overall impact of medical errors on outcomes (although severity adjustment and rigorous methods may help produce estimates for specific processes of care).

CONCLUSION

The summary of the results of this study are

I) Disease burden in general medical wards in our hospital in 2005 were similar to our country's profile with infectious disease being the leading cause. The death rate in general medical wards was 8.1%.

II)

a. The likely medical error related deaths occurred in 11% of all deaths in the general medical wards.
b. 75% of the medical error related occurred due to system faults. Nosocomial infections(42%) are the predominant cause.
c. The occurrence of a likely medical error related deaths increases as the duration of stay in hospital becomes longer than seven days.

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ANNEXURES

ANNEXURE – 1
A MORTALITY STUDY OF GENERAL MEDICAL PATIENTS

S.No: Name: Age: Sex:

Occupation: Hospital No.: Address:

Death Date: Death Time: Day of the Wk.:

Place of Death: Casualty /B Ward /C Ward/E Ward/ICU/Others

Mode of Death: (i) Natural

(ii) Unnatural – Suicide / Murder / Assault /All Accidents

(iii) Others

Classification by cause of death [ICD – 10]

(A). Immediate cause ----------

Antecedent cause----------

Underlying cause----------

(B) Other causes ----------

Classification cause of death by ICD – 10

I Infectious and parasitic disease

II Neoplasm

III Blood and Blood forming organs and certain disorders involving, nutritional immune mechanisms

IV Endocrine, Nutritional and Metabolic disease

V Mental and Behavioral disorder

VI Nervous system

VII Eye and Adenexa

VIII Ear and Mastoid Process

IX Circulatory system (including CVA)

X Respiratory system

XI Digestive system

XII Skin and subcutaneous tissue

XIII Musculoskeletal system and connective tissue

XIV Genito-urinary system

XV Pregnancy, Childbirth and puerperium

XVI Conditions originating in perinatal period

XVII Congenital malformations, deformations and chromosomal abnormalities

XVIII Symptoms and signs of abnormal clinical and lab findings not elsewhere classified

XIX Injury, poisoning and certain other consequences of external cause

XX External cause of Morbidity and Mortality.

Co-morbid factors – Y / N

A. Patient

a. Smoking

b. Alcohol

c. Diabetes Mellitus

d. Hypertension

e. Hyperchol

TC
TG > 200

LDL in diabetes - > 100

f. Obesity BMI > 30

g. Ischaemic Heart Disease

h. Peripheral Vascular Disease

i. Others

B. Hospital

a. Adverse Drug reaction

b. Pressure sores

c. Nosocomial infections

d. Complication of Invasive procedure

e. Others

C. Environmental

a. Falls
b. Transport Accident
c. Industrial Lung disease
d. Exposure Toxic chemicals
e. Others

D. Unnatural

a. Suicide / Murder / Assault
b. Accidents - Home / Work / Road Traffic Accidents
c. Others

Source of Admission

a. OPD
b. Casualty
c. ICU
d. Others

Duration of Hospital stay prior to death (If < 1 day, then Time in hours)

End of Life event

Was admission for Terminal care Y/ N

a. If Yes name of Disease----------

b. Duration of hospital stay prior to death ----------

Was DNR order accepted by the Medical team and relatives Y / N

Was resuscitation attempted Y / N

Was death unexpected Y / N

(Without prior DNR order and failed resuscitation)

Was death sudden Y / N

Details of Critical event (Circle Below)

A. Bedside Physiological Parameters:

1) BP systolic < 100 mm Hg or 200 mm Hg

2) Heart rate < 60beats/mt or > 120beats/mt
3) Temperature < 35.5^0C or > 38.5^0C
4) Urinary output < 200ml / 12hours
5) Respiratory rate < 10 breath/mt or > 25 breaths/mt
6) O_2 saturation < 90%
7) Glasgow coma scale < 12

B. Biochemical laboratory Parameters:

1) Creatinine > 1.5 mg/dL
2) Sodium < 130meq/L or > 150 meq/L
3) Potassium <3.0 meq/L or > 6meq/L
4) Pao_2 < 70 mm Hg
5) $Paco_2$ > 45 mm Hg
6) Arterial standard base excess > ± 4 mmol/L

C. Pathological laboratory Parameters:

1) White cell count >20,000cells/mm^3 or < 2000cells/mm^3
2) Hemoglobin < 9g/dL
3) Platelet count < 50,000/ mm^3
4) International Normalised Ratio > 2.5

Others

a. All Accidents
b. Suicide / Murder / Assault

Did any adverse event occur: Y / N

a. Date
b. Time
c. Cause (Circle Appropriately)
   i. Complication of invasive procedure. Specify----------
   ii. Adverse Drug reactions. Specify----------
   iii. Human Error
      a. Judgement error b. Technical error
      c. Vigilance error d. others

GLOSSARY TO THE DATA SHEET:

1. Hospital number (Hosp. No.)
2. Age
3. Sex
4. Date of death (death date),
5. Time of death (deathtime)
6. Place of death (placedth)
7. Unnatural factors
8. Type of admission (typeadmn)
9. Duration of hospital stay (durhstay)
10. Immediate cause of death
11. Antecedent cause of death
12. Other causes of death
13. ICD code
14. Environmental factors
15. Admission Palliative care (admission Palliative care)
16. Was the Do Not Resuscitate (DNR) accepted? (DNR accepted)
17. Was resuscitation attempted? (resuscitation attempted)
18. Unexplained cause of death (unexp)
19. Physiological parameters
    - Temperature
    - Systolic Blood Pressure (SBP)
    - Saturation of Oxygen in blood (O2)
    - Respiratory Rate (RR)
    - Glasgow Coma Scale (GCS)
    - Heart Rate (HR)
    - Urine Output (UO)
20. Laboratory parameters

- Hemoglobin (Hb)
- Total leukocyte Count (WBC)
- Platelet Count (plt)
- Glucometer Random Blood Sugar (GRBS)
- Lactate Dehydrogenase (LDH)
- Serum Creatinine (S.Creat)
- Serum Sodium(S.Na)
- Serum Potassium (S.K)
- Troponin – I (trop-I)
- Uric acid
- Liver Function Tests (LFT)
- Cérébrospinal Fluid Analysis (CSF)

21. Diabetes Mellitus (dm)

22. Hypertension (htn)

23. Smoking

24. Alcohol

25. Dyslipidemia (dyslipid)

26. Bronchial Asthma/COPD (Bacopd)

27. Ischemic Heart Disease (ihd)

28. Acquired Immune Deficiency Syndrome (aids)

29. Cerebro-Vascular Accident (cva)

30. Thyroid dysfunction (thyroid)

31. Lymphoma

32. Rheumatic Heart Disease (rhd)

33. Tuberculosis (tb)

34. Hepatic dysfunction (hepdis)

35. ICD codefor all causes of death (allccode)

36. ME ; Medical Error

37. typ : Type of medical error